

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

IN RE: ANDROGEL ANTITRUST)
LITIGATION (NO. II)) Docket No. 1:09-MD-2084-TWT
January 7, 2010
Atlanta, Georgia
2:03 p.m.

TRANSCRIPT OF THE MOTIONS HEARING
BEFORE THE HONORABLE THOMAS W. THRASH, JR.,
U.S. DISTRICT COURT JUDGE

APPEARANCES OF COUNSEL:

On behalf of the Plaintiffs: Ken Canfield
Bruce Gerstein
Markus Meier
Corey Holzer

On behalf of the Defendants: Mark Ryan
Steven Sunshine
Teresa Bonder
Mark Gidley
Eric Grannon

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SUSAN C. BAKER, RMR, CRR
2194 U.S. COURTHOUSE
75 SPRING STREET, S.W.
ATLANTA, GA 30303
(404) 215-1558

1 (Proceedings held in Atlanta, Georgia, January 7,
2 2010, 2:03 p.m., in open court.)

3 THE COURT: All right. This is the case of In Re:
4 AndroGel Antitrust Litigation, 09-MD-2084.

5 Normally I ask counsel for the parties to introduce
6 yourself and the parties you represent, but given the numbers I
7 see out there I think I'll just wait and let you introduce
8 yourselves when and if you say anything.

9 As I said, this is a hearing -- or it is a hearing on
10 the motions to dismiss in these cases. What I propose to do is
11 to give the Defendants collectively an hour and the Plaintiffs
12 collectively an hour.

13 With that understanding, do the Defendants have any
14 agreement among yourselves as to who's going to speak and for
15 how long?

16 MR. RYAN: Your Honor, Mark Ryan on behalf of Solvay.

17 Yes, we do. We're going to divide up the arguments.
18 And when I -- I'm going to go first, and I will explain to the
19 Court at the podium how we are going to do it. And we are
20 going to save some time for rebuttal as well, so we won't take
21 the whole hour on our initial presentations.

22 THE COURT: All right. How about the Plaintiffs,
23 y'all have some understanding of how you are going to divide
24 your time up, Mr. Canfield?

25 MR. CANFIELD: We do, Your Honor. I am going to

1 speak very briefly, and then Markus Meier from the FTC will be
2 presenting their position. And Bruce Gerstein will be
3 presenting the private Plaintiffs' position.

4 THE COURT: All right. Unfortunately, I'm going
5 to --

6 MR. HOLZER: Your Honor, excuse me. I am Corey
7 Holzer on behalf of the end-payer Plaintiffs. We would simply
8 ask for five minutes of the Court's time if needed.

9 THE COURT: Well, I'm going to strictly enforce the
10 hour limit. With the number of parties, the number of claims,
11 the number of defenses and the number of arguments that are
12 being made, if I don't it'll just go on forever and we'll all
13 be snowbound here for the next couple of days. So however it
14 works out, if the Plaintiffs' time is up it's going to be up.

15 MR. HOLZER: I understand.

16 THE COURT: And it's the same for the Defendants.

17 All right. The Defendants have the burden on the
18 motions, so I'll hear from you first.

19 MR. RYAN: Thank you, Your Honor. Again, it's Mark
20 Ryan on behalf of Solvay Pharmaceuticals.

21 Your Honor, I am going to address the question of why
22 the 11th Circuit decision in Schering-Plough requires a
23 dismissal of the FTC complaint. Mr. Sunshine will explain why
24 the allegations of sham patent litigation set forth in the
25 direct purchaser complaints are insufficient as a matter of

1 law.

2 Now, Your Honor, I'd like to point out that once the
3 sham allegations are dismissed the private Plaintiffs will find
4 themselves in the same boat as the FTC Plaintiffs -- as the FTC
5 is with respect to Schering-Plough. The FTC, of course, had a
6 lengthy investigation two years with depositions and document
7 productions; and they have not alleged that the underlying
8 patent litigation that occurred before Your Honor was a sham.
9 Only the private Plaintiffs in an effort to plead around
10 Schering-Plough have done that. Stripped of those allegations,
11 the sham allegations, the private Plaintiffs' complaints are
12 equally and fully subject to dismissal under Schering-Plough.

13 Finally, counsel for Par and Paddock is going to
14 explain why the claims against those Defendants are subject to
15 dismissal on additional grounds.

16 As I pointed out, Your Honor, I am going to try to
17 save time for rebuttal.

18 THE COURT: All right.

19 MR. RYAN: Your Honor, this is really a case about
20 the applicability in the rule of Schering-Plough which was
21 announced by the 11th Circuit and then re-announced in the
22 Andrx case before the 11th Circuit. The standard is the proper
23 analysis quoting from the case of antitrust liability requires
24 an examination of: One, the scope of the exclusionary
25 potential of the patent; two, the extent to which the

1 agreements, that is to say the settlement agreements, Your
2 Honor, exceed that scope; and, three, the resulting
3 anti-competitive effects.

4 So in somewhat plainer language, Your Honor, what is
5 the task before this Court?

6 On the one hand, the Court should look to see what
7 the allegations are about the exclusionary potential or the
8 scope of the patent at issue in this case. Then on the other
9 hand, the Court examines what the allegations are about the
10 scope of the exclusion, alleged exclusion of competition under
11 the settlement agreements. And then the question becomes do
12 the settlement agreements in any way expand the exclusionary
13 power or potential of the patent. If the settlement agreements
14 do not do that, that is to say they do not extend the power of
15 the patent, then the case is at an end and the complaint must
16 be dismissed.

17 Now, Your Honor, the FTC complaint and the private
18 complaints are clear that the patent in this case expired in
19 the year 2020. It's also clear and undisputed that the
20 settlement agreements allow generic competition to begin in
21 2015. So with respect to the temporal scope of the patent,
22 there's no dispute that the agreements are within, that is to
23 say they are less than, the right to exclude granted by the
24 patent.

25 With respect to the product at issue here, the FTC

1 complaint and private complaints are clear that the patent
2 concerned the drug AndroGel. The settlement agreements concern
3 generic AndroGel. There's no claim in this case, Your Honor,
4 that the settlement agreements -- there's no claim in this case
5 the settlement agreements concern any other drug than the drug
6 that is the subject of the AndroGel patents or AndroGel patent.

7 Your Honor, those facts which appear in the pleadings
8 and this Court's task -- because absent some allegation that
9 the power of the patent has been extended via the settlement
10 agreements, beyond what the patent itself provides the case is
11 in an end. And that's the rule of Schering-Plough. That's the
12 rule of Andrx.

13 And, Your Honor, I want to point out that there are a
14 couple of places in the FTC brief that we are in complete
15 agreement with. On page 2 of their brief, the FTC explains --
16 this is the opposition to the motion to dismiss. The FTC
17 explains that in the past -- they say to be sure in the past
18 the FTC has interpreted Schering-Plough precisely the way the
19 Defendants in this case interpret Schering-Plough in our moving
20 papers. And on page 28 of their brief, the FTC acknowledges
21 that two other Federal Circuits, the Federal Circuit and the
22 2nd Circuit, take the same view of the rule of law as
23 Schering-Plough.

24 Now, the FTC doesn't point out but it's clear in
25 those cases that those cases actually relied on the analysis in

1 Schering-Plough. They looked to what the 11th Circuit had done
2 in arriving at the same result.

3 So, now, where did the FTC make these other
4 statements?

5 One of the places they made these statements was to
6 the Supreme Court of the United States when they sought
7 reversal of the Schering-Plough decision. And the FTC in that
8 paper describes Schering-Plough as a case that, "effectively
9 immunizes all payments to delay generic competition provided
10 the delay does not extend beyond the nominal scope of an
11 untested patent unless the patent claim is an obvious sham or
12 the patentee knew that his claim was without merit."

13 So that's the way prior to its papers in this case
14 that the FTC described the scope of Schering-Plough. And they
15 don't make any claim as I said about sham, and they don't
16 allege that Solvay knew that its patent was without merit. So
17 under their previous view of the case, they would agree with us
18 that the case would be at an end.

19 Now, the other places where the FTC has expressed
20 agreement with our view of Schering-Plough are congressional
21 testimony and in public speeches by commissioners. And in our
22 briefs, Your Honor, we cite the Court to where those statements
23 can be found.

24 So we have a situation where you have
25 Schering-Plough, you have Andrx, you have the Tamoxifen case in

1 the 2nd Circuit and you have the Cipro case in the Federal
2 Circuit, all of which -- in the FTC's own statements all of
3 which are on the same page. You also have a District Court
4 decision, a recommendation of a special master that we cite in
5 our papers from the District of New Jersey and a State Court
6 case involving the Cipro product in California. All of these
7 authorities agree on what the meaning of Schering-Plough is.

8 So what that leaves us with is the FTC position in
9 this case that the Court should seize on -- and there's
10 remarkably little attention paid, I believe, to the Schering
11 decision in the Government's brief here. But they seize on a
12 sentence fragment in the concluding paragraph of the
13 Schering -- of the 11th Circuit decision and say, Well, the
14 Court is supposed to evaluate the strength of the patent.
15 That's what they ask this Court to do. And what they're asking
16 the Court to do is to have a trial, a trial on the merits of
17 the AndroGel patent.

18 Your Honor, that position cannot be reconciled with
19 the entire thrust and language and subsequent history, if you
20 will, of the Schering-Plough decision. And I think as a
21 practical matter and as I'm sure the Court is aware if the law
22 were -- and this is what the 11th Circuit recognized -- if the
23 law were that patent settlements could be attacked because the
24 Federal Trade Commission or private parties wish to bring
25 antitrust claims essentially alleging that the patent holder

1 would have lost or could have gotten a better result or that
2 the Defendants, the generic companies could have gotten a
3 better result in patent litigation and we'd be exposed to
4 government sanction or treble damages, it would make it very
5 difficult, if not impossible, to settle patent cases.

6 And as the Court observed in Schering, and I'll quote
7 from the decision, "The general policy of the law is to favor
8 the settlement of litigation, and the policy extends to the
9 settlement of patent infringement suits. Patent owners should
10 not be in a worse position by virtue of the patent rights to
11 negotiate and settle surrounding lawsuits."

12 So, Your Honor, at the end of the day we have a very
13 straightforward request of this Court which is simply to apply
14 what we believe is the clear rule of Schering-Plough. And we
15 recognize that the FTC may disagree with that result, that they
16 do disagree with the result in Schering-Plough. But in all due
17 respect to the Federal Trade Commission and to the private
18 Plaintiffs, this is not the forum in which to express
19 disagreement with the 11th Circuit. They have to take that
20 argument elsewhere. As, of course, as Your Honor is aware,
21 this Court is bound to apply the 11th Circuit law.

22 So, Your Honor, that concludes my opening remarks if
23 the Court doesn't have any questions.

24 THE COURT: All right, Mr. Ryan.

25 MR. RYAN: Thank you. I'll turn it over to

1 Mr. Sunshine.

2 MR. SUNSHINE: Good afternoon, Your Honor. Steve
3 Sunshine for --

4 THE COURT: Good afternoon, Mr. Sunshine --

5 MR. SUNSHINE: -- Watson Pharmaceuticals.

6 Mr. Ryan just ably explained why the FTC's complaints
7 against the Defendants fail as a matter of law under
8 Schering-Plough. As he noted, the same argument applies in
9 part to the private Plaintiffs' complaint. But where the
10 private Plaintiffs have parted company from the FTC is that
11 they have taken a giant step. They have alleged something that
12 the FTC despite its long investigation has never alleged or, in
13 fact, even hinted at. And that's namely that the three-year
14 patent litigation that occurred before Your Honor was, in fact,
15 completely baseless and a sham.

16 And, moreover, these baseless litigation claims which
17 if they are true would have been of a Grade A to this case
18 initially for the private Plaintiffs were never included in the
19 California complaint that they first filed. It was only upon
20 the transfer to this court to Your Honor that those claims were
21 included.

22 We think it's apparent that the private Plaintiffs
23 have added these baseless litigation claims to try to drive
24 this case into this very narrow exception recognized by the
25 11th Circuit in Schering-Plough. Nevertheless, we believe that

1 these baseless litigation claims should be dismissed as a
2 matter of law at this stage.

3 I understand that, you know, Plaintiffs will have
4 argued in their opposition papers and I expect will argue today
5 that the complaint contains enormous detail. There are a
6 number of factual allegations. But I'm going to summarize
7 briefly today --

8 THE COURT: Let me interrupt you, Mr. Sunshine.

9 Do you interpret the indirect purchasers as asserting
10 a sham litigation claim in their complaints?

11 MR. SUNSHINE: Your Honor, I believe that there are
12 three indirect purchaser complaints. Two of them I don't
13 believe include any allegations. I think one FOP, Fraternal
14 Order of Police, has what I believe is one conclusory
15 allegation of sham litigation. So whether it's in that --
16 whether it's in FOP or not, because I do think as I'll mention
17 that one conclusory allegation can pretty quickly be ignored
18 for purposes of the motion to dismiss.

19 THE COURT: All right, Mr. Sunshine.

20 MR. SUNSHINE: Okay. Thank you.

21 Your Honor, the point that I was making was
22 despite -- and I'm sure we'll hear this argument from the
23 Plaintiffs today. We certainly saw it in their opposition
24 papers that there's an enormous amount of factual detail in the
25 complaint. But for three different reasons that we'll pull

1 together today and explain, this case still should be dismissed
2 at this stage. And I'll explain them in more detail.

3 But it's really the combination of Twombly and Iqbal
4 which provides the plausibility standard, the Professional Real
5 Estate Developers case which is a Supreme Court case on what
6 this high standard is for baseless litigation, and third and
7 most importantly is this Court's own experience with the patent
8 litigation and the record in the underlying litigation. When
9 put --

10 THE COURT: You're right, Mr. Sunshine. It's the FOP
11 case that says Unimed engaged in sham litigation. That's all
12 it says. That's the substance. I mean, that's the total of
13 what it said.

14 MR. SUNSHINE: I agree, Your Honor. And I think you
15 can dispatch that allegation very quickly under Iqbal but even
16 if we were to accept that allegation in the FOP complaint that
17 it fails for the same reasons as we're talking about here with
18 respect to the direct purchaser complaints.

19 In putting these factors together, Twombly, Iqbal,
20 PRE and the underlying patent litigation, as we have suggested
21 to you in the papers there's two separate levels we can look at
22 why these complaints aren't plausible. First, as the Supreme
23 Court commanded, we can look in context and we can see all the
24 reasons why these baseless litigation claims don't make any
25 sense in this context. Secondly, we can look at the actual

1 status of the underlying patent litigation and look at it just
2 long enough to understand that there was actually a dispute and
3 a fight there. And so at both levels I think we can dispose of
4 the case or Your Honor can dispose of the case on either of the
5 levels. And, of course, taken together we would certainly
6 suggest to Your Honor that dismissal is mandated here.

7 Before jumping into those two arguments about the
8 context of this entire litigation shows it's implausible and
9 the status of the underlying litigation, I'd like to just
10 mention a couple of key points about the legal standard.
11 Twombly and Iqbal have been the law now for a couple of years.
12 I know there's various schools of thought about how much
13 Twombly and Iqbal changed and how much it may have codified
14 existing practice, but I think it's fair to say that after
15 Twombly and Iqbal it's clear that the Supreme Court expects
16 that there be a plausibility standard.

17 In Twombly the Supreme Court ruled that an antitrust
18 cause of action can't be pled in a conclusory fashion but must
19 state a claim for relief that's plausible on its face. Iqbal
20 as we were just saying, Your Honor, just made it clear that the
21 Court need not accept any legal conclusions in evaluating the
22 motion to dismiss. And, finally, and what I think is an
23 important point and perhaps just recognizing what trial courts
24 do all the time in Iqbal the Supreme Court said that the
25 determination of plausibility is context specific and the trial

1 court must draw on its experience and common sense in deciding
2 whether these claims are plausible. In total and in another
3 point, the Supreme Court has said the complaint in its context
4 must nudge the claim for relief from possible to plausible.

5 Turning to --

6 THE COURT: If somebody could tell me exactly what
7 that means, I would really appreciate it.

8 MR. SUNSHINE: Well, fortunately, in this case, Your
9 Honor, we are nowhere close to that line. But I understand
10 that not everybody reads Twombly and Iqbal as being quite as
11 path-breaking as perhaps others do.

12 Turning to PRE, that opinion is an opinion by Justice
13 Thomas of the Supreme Court; and that opinion sets out the
14 standard for when something must -- for what qualifies as
15 baseless litigation. And Justice Thomas and the Supreme Court
16 in that opinion were very concerned about the chilling effect
17 of allowing antitrust claims to be brought when litigants are
18 seeking access to the Court. So the Supreme Court purposely
19 set a very high standard.

20 The PRE standard has two elements. One's objective.
21 One's subjective. The objective test -- and this is a test
22 akin to Rule 11 -- is that the claim must be objectively
23 meritless. The Supreme Court in another point says that no
24 reasonable litigant could realistically expect any chance of
25 success, again, akin to a Rule 11 standard, very high, very

1 difficult standard.

2 When you take, I think, the PRE standard together
3 with the Twombly standard, what it says is for a baseless
4 litigation claim to survive in the underlying litigation,
5 underlying patent litigation in this case there needs to be no
6 determinative legal issues and no genuine disputes of fact.
7 And what we'll argue to Your Honor as we go through some of
8 this patent litigation, there's one thing that the history of
9 the patent litigation shows is that it was highly disputed and
10 highly contested.

11 And, in fact, there's in the opposition papers of
12 Plaintiffs I think that they make the claim that since there
13 were factual disputes from the Plaintiff and this is a motion
14 to dismiss in the antitrust case, therefore, you can't grant a
15 motion to dismiss when there's factual disputes. But I think
16 that misses the point, and I would suggest that in that case
17 they're just wrong. Because we're talking about the underlying
18 patent litigation and whether or not that was baseless, to the
19 extent there were factual disputes in the underlying patent
20 litigation if you then apply the PRE standard to the underlying
21 patent litigation as a matter of law the case can't be baseless
22 if indeed those factual disputes existed.

23 Okay. With that said about the legal standard, let
24 me turn to the two arguments, one, the context sets of
25 arguments and, two, the status of the underlying patent case.

1 In the context arguments, I won't dwell on these. We go
2 through many or we go through all of them in the papers.

3 But how do we know from the facts of this entire case
4 and proceeding that these claims are baseless?

5 First, as this Court is more than aware having
6 supervised the underlying patent litigation for over three
7 years, it was hard fought. It was complicated. It was
8 protracted. It was contested. There were hundreds of
9 thousands of documents exchanged, 15 experts on all sides of
10 all issues, 27 fact witnesses. And akin to the discussion we
11 just had on Twombly and PRE, the case was headed to the
12 fact-finder. There were no dispositive legal issues. There
13 was no full summary judgment motions. All the summary judgment
14 motions were partial. Even if the Defendants had won every
15 last summary judgment motion, the case still would have had to
16 go to the fact-finder.

17 Second, I think this is also a very interesting
18 point. Peculiarly, the Plaintiffs in this case, in the
19 antitrust case, the way they have come at their allegations of
20 the baseless litigation is to do something pretty curious.
21 They have copied all of the Defendants' arguments or most of
22 the Defendants' arguments in the underlying patent case, so
23 they have basically taken one side of the caption and basically
24 said everything on this side of the caption is correct or a
25 right position. And then the other side, the Solvay side they

1 either ignore or they slap a conclusory label on it that if
2 Solvay argued it was baseless and so it doesn't count for
3 anything.

4 We would submit to the Court that the Court need not
5 indulge in that exercise. First, the mere labeling of the
6 Solvay positions as objectively baseless fails under the Iqbal
7 test. That conclusory allegation can be stripped right out of
8 the case. Second, this slight of hand would basically render
9 any subsequent antitrust attack on the litigation would mean it
10 could never get dismissed on a motion to dismiss context
11 because you could always adopt the one side of the caption and
12 say the other side of the caption is baseless; and that's not
13 the case. And that's why I think again the Supreme Court in
14 the teaching in Iqbal about putting everything together in
15 context and making it plausible is so relevant to this
16 particular case.

17 Third fact, this Court entered a consent judgment
18 with respect to the settlement of Par and Paddock and Solvay.
19 And under the prevailing law of this circuit, a consent
20 judgment can only be entered if the Court determines that's a
21 reasonable factual and legal determination based on the record.
22 I think the only point we are trying to make here is that it
23 was a reasonable settlement. As Mr. Ryan indicated, the patent
24 expiration was 2020. The settlement date provided for 2015.
25 It was a midrange and clearly a reasonable settlement of that

1 underlying dispute.

2 Fourth, as I alluded to earlier, the fact that the
3 Plaintiffs only added the sham litigation claim when they were
4 before this Court and subject to the Schering-Plough precedent
5 certainly is a relevant fact in understanding the context of
6 this case.

7 Fifth, the actions of the generics themselves. The
8 generics fought this case for three years. The generics never
9 pursued a Rule 11 motion. They never pursued an abuse of
10 process motion. While there was a boilerplate allegation in
11 the answer, there was never any pursuit of an antitrust
12 counterclaim. Watson had the right to launch at risk after the
13 expiration of the 30-month stay. It never did it. I
14 acknowledge, Your Honor, that none of these facts is
15 dispositive as a matter of law; but they are all highly
16 relevant facts under the Iqbal context specific test that the
17 Supreme Court has said that should apply here.

18 And, finally, in the context point we have the
19 investigation of the FTC. Mr. Ryan already noted that the FTC
20 has made it one of its policy missions to try to overturn the
21 Schering-Plough case. The FTC did a very extensive
22 investigation. They collected millions of documents from all
23 three Defendants or in the aggregate collected millions of
24 documents from the three Defendants. They took investigatory
25 hearings which are essentially depositions of over 20 party

1 witnesses. They took third-party witnesses. And despite all
2 of this investigation, the FTC has not alleged baseless
3 litigation.

4 The private Plaintiffs, Your Honor, however, have;
5 and the private Plaintiffs have had access to no non-public
6 materials. The private Plaintiffs have only seen the
7 underlying patent record and whatever allegations were in the
8 FTC complaint and perhaps whatever the public investigations
9 they've done. But, again, an important factor.

10 As I have just mentioned, that brings all the list of
11 context factors. We recognize that any one of those context
12 factors does not necessarily mandate as a matter of law that
13 the case be dismissed. But these are the kind of factors that
14 the Supreme Court is looking for the Court to -- the trial
15 court to apply in its common sense. And I think taken together
16 in the aggregate all of these context factors just provided an
17 overwhelming picture that these baseless litigation claims are
18 an afterthought and should be dismissed.

19 If I turn briefly, and I'll do this very briefly from
20 the objective -- from the context arguments to looking at the
21 underlying patent merits, I won't repeat all of how hard fought
22 and how protracted the underlying litigation was. But I think
23 it is important again to note that the case as it was sitting
24 before Your Honor on the day it was settled was headed to the
25 fact-finder no matter what Your Honor decided. And that if we

1 go back to the PRE standard means that the case can't be
2 objectively baseless.

3 And I think it's important that what we're saying to
4 Your Honor particularly at this stage is not that you have to
5 get into the merits of the underlying patent litigation. You
6 don't have to decide who was right and who was wrong. You
7 don't have to decide the patent issues. I think the only thing
8 that Your Honor need do is look at the underlying record, draw
9 on your experience and just acknowledge that it was a dispute.
10 And I'm happy, Your Honor, to go through each of the four legal
11 issues that were in dispute there. They're in the brief. I
12 think there are obviously two sides to that story. But I won't
13 do that unless Your Honor has questions on the specific merits.

14 Let me sum up and just say that the Plaintiffs are
15 essentially asking this Court to disregard everything that it
16 knows from the patent litigation. They're asking this Court to
17 look at one side of the caption, that the allegations that are
18 made are merely copied out of the Plaintiffs' complaint.
19 There's nothing in the Plaintiffs' complaints about the
20 baselessness of the litigation that don't come from arguments
21 the generics made, yet the generics never took the steps that
22 the private Plaintiffs are taking here. And labeling -- the
23 conclusion on Solvay's side of the argument is just a legal
24 conclusion that is not entitled to any deference by this Court.

25 So we would suggest to this Court on the basis of

1 both those arguments, either one of those arguments and
2 certainly the two together that this Court should dismiss the
3 Plaintiffs' baseless litigation claims at this stage.

4 Thank you, Your Honor.

5 THE COURT: Thank you Mr. Sunshine.

6 MR. GIDLEY: Your Honor, Mark Gidley for Par and
7 Paddock.

8 Your Honor, Par and Paddock join in the arguments
9 made about the trilogy of 11th Circuit precedent with a
10 settlement that takes five years off the patent making this
11 case ripe for dismissal solely on the proposition of
12 Schering-Plough. And, further, Your Honor, as far as the sham
13 argument in addition to the points made in the foregoing
14 presentation, it's also the case that as a generic Defendant we
15 can only be the victim of any kind of sham litigation. Of
16 course, Your Honor having lived through this for three years
17 knows there was no sham litigation. However --

18 THE COURT: Well, Mr. Gidley, I have got a question
19 about that. I mean, clearly if it is sham litigation in the
20 sense that a patentee is suing a competitor and the allegation
21 is that the holder of the patent is engaged in sham litigation
22 obviously it's only the holder of the patent that can do that.
23 But in the context of whether or not there's an exception to
24 the Schering-Plough doctrine, I'm not quite so sure that your
25 argument about you can't be liable is supported in the case

1 law.

2 MR. GIDLEY: Well, Your Honor, let's assume for a
3 second that there is some kind of a sham exception. I think
4 whatever that sham exception is -- and the 11th Circuit hasn't
5 had a case with a holding saying this one was a sham -- it
6 would nonetheless be constrained by the Supreme Court's
7 objectively basis and subjective factors. Here, Your Honor --

8 THE COURT: Well, I think that's right. That PRE
9 case, that did involve as I recall a claim where it was the
10 filing of the litigation itself that was the alleged antitrust
11 violation. Here I think what the Plaintiffs are arguing is
12 it's not the settlement of the litigation that's the antitrust
13 violation, it's the agreement about dividing up the market
14 which is the antitrust violation which you are a party to.

15 MR. GIDLEY: That's right, Your Honor.

16 And maybe I should go to the heart of the matter and
17 make sure if I have not addressed the Court's question I can
18 circle back to it. But the way we look at it is twofold.
19 First, we are entitled to the effective immunity that the FTC
20 argued the Schering-Plough case grants us under
21 Schering-Plough. That's point one. But point two is we are
22 entitled to the absolute immunity as the Supreme Court called
23 it in Allied Tube that attaches with Noerr-Pennington. And the
24 crux there, I think the fulcrum for the argument is does the
25 consent judgment entered into the patent settlement, the

1 resolution for Par and Paddock, does it disclose an order that
2 we refrain from practicing the patent art until 2015. Indeed,
3 it does, Your Honor. The order at paragraph 6 details the
4 entry date conditions for entry by Par or Paddock in 2015 or
5 2016. And, in fact, we're ordered not to practice the patent
6 unless the 6(b) condition, another generic entry occurs.

7 We believe it is clear under the case law -- and I
8 will give you the precedence. We primarily rely, Your Honor,
9 on MedImmune and Andrx Pharmaceuticals; but it's conceded by
10 the FTC the judicial action like any other governmental action,
11 action by Congress, that sort of action once it's done, once
12 there's valid governmental action immunity attaches.

13 Here, Your Honor, we subjected ourselves to a consent
14 judgment. We could have simply done a settlement agreement,
15 but Par and Paddock submitted to the Court's jurisdiction.
16 And, in fact, Par was not a party in the patent infringement
17 case. It showed up and said, Your Honor, here's the deal,
18 we've got a resolution with this branded company and we can
19 come in in February of 2016 and under some circumstances August
20 of 2015. And we proposed that consent judgment.

21 Your Honor ordered that consent judgment which had
22 the following legal effects under Stovall and other precedence
23 of the 11th Circuit. First, Your Honor, the consent judgment
24 unlike a mere settlement resolution is res judicata of the
25 matter City of Miami, 5th Circuit, 1981. Second, Your Honor,

1 we submitted ourselves to the scrutiny and continuing
2 jurisdiction of this Court. So if the Court had questions
3 about the resolution, the Court was free to do that. We were
4 not going to get this consent judgment approved without
5 satisfying the Court.

6 Third, we are under an injunction. Your Honor's
7 order, the consent judgment, is a future injunction. As
8 Stovall puts it at 1242: By virtue of its injunctive
9 provisions, a consent decree reaches into the future and has
10 continuing effect.

11 Fourth, of course, if we violated Your Honor's
12 consent judgment, that would be punishable by contempt.

13 Now, the complaints allege only an agreement
14 postponing generic entry until 2015 and 2016. The FTC's right
15 upfront about that. Paragraph one of the FTC's second amended
16 complaint: This case challenges agreement by Watson, Par and
17 Paddock to delay until 2015 the sale of low-cost generic
18 AndroGel.

19 Similarly, the direct class purchasers, paragraph
20 two: Solvay entered into agreements with the generic
21 Defendants. Through these agreements, the generic Defendants
22 agreed not to compete with Solvay's AndroGel product until at
23 least 2015.

24 And, similarly, Your Honor, the same allegation
25 appears in the indirect purchaser complaint. That's paragraph

1 two of the Fraternal Order complaint, paragraph ten of the
2 Scurto complaint and paragraph 71 of the UFCW complaint. The
3 gravamen of this case is an agreement by the parties which
4 restrains generic entry until 2015. That's exactly what order
5 paragraph 6 and A, B and C does.

6 The case law and the two cases that we rely primarily
7 on on this point, Your Honor, certainly, of course, judicial
8 resolutions are part of the Noerr-Pennington doctrine. That's
9 conceded by the FTC. California Motor Transport, the Andrx
10 opinion by the 11th Circuit has held to that fact. It applies
11 in this context. Andrx Pharmaceutical versus Biovail, Your
12 Honor, at 818 -- and this is the D.C. circuit Andrx. It's
13 confusing. There are two Andrx. If an anti-competitive harm
14 is caused by a decision of the Court even though granted at the
15 request of a private party, no private restraint of trade
16 occurs because the intervening governmental action breaks the
17 causal chain.

18 And, similarly, the MedImmune decision in California
19 states: Unlike settlement agreements under 41(a), a consent
20 judgment means the very anti-competitiveness of the agreement
21 depends on the government exercising its discretion to create
22 an anti-competitive result.

23 We certainly are immune under the effective immunity
24 of Schering-Plough. We are also entitled to the immunity, Your
25 Honor, of the Noerr-Pennington doctrine.

1 And with that, Your Honor, we'll reserve the rest of
2 our time on rebuttal. But my colleague, Mr. Grannon, would
3 address the second and final argument.

4 MR. GRANNON: Good afternoon, Your Honor. Eric
5 Grannon for Par Paddock.

6 I will briefly address, Your Honor, our second filer
7 argument which we believe is another independent basis for
8 dismissal of Par Paddock and, frankly, Your Honor, an important
9 means for insulating these smaller companies from the FTC's
10 stated desire for a litigation vehicle to overturn the
11 circuit's precedent. Just very briefly, Your Honor, if it's
12 helpful to the Court, I will draw the Court's attention on the
13 point Your Honor raised about the applicability of sham
14 allegations to the generic Defendants and what that means to
15 the Schering-Plough standard.

16 At pages 18 through 19 of our motion to dismiss
17 against the direct purchasers, Your Honor, we go into some
18 detail about why we think that doesn't make sense and how it
19 would not make sense to impose a burden on generic Defendants
20 to somehow investigate the objective and subjective basis for
21 the patent holders' enforcement and why we think that would not
22 be workable, Your Honor.

23 On the second filer point, Your Honor, it basically
24 boils down to three points demonstrating that the FTC and the
25 private Plaintiffs have not plausibly alleged harm to

1 competition from second ANDA filer Par Paddock entering at the
2 same time as first filer Watson. First, Your Honor, it's
3 Congress that designed the Hatch-Waxman regulatory scheme being
4 the first ANDA filer had 180 days of marketing exclusivity, a
5 monopoly, if you will, and thereby also keeps all subsequent
6 ANDA filers off the market until after a first filer's entry,
7 Your Honor.

8 Second, because of this Hatch-Waxman regulatory
9 structure, even accepting, Your Honor, the FTC's theory that
10 settlement providing for generic entry prior to patent
11 expiration, that that entry prior to patent expiration could
12 nonetheless somehow cause anti-competitive delay, a second
13 filer settlement, Your Honor, could only cause such delay if it
14 provided for entry by the second filer after the first filer.

15 Third, and, finally, Your Honor, ignoring this
16 regulatory scheme, the FTC's and private Plaintiffs' sole
17 allegations of competitive harm against Par Paddock are a
18 series of hypothetical scenarios in which Par Paddock would
19 have entered earlier. For reasons I'll address briefly, Your
20 Honor, we respectfully suggest that these hypotheticals should
21 not be entertained by the Court. And in any event, each is
22 implausible.

23 Briefly, Your Honor, on the first point I will spend
24 just a moment on the operation of the first filer's 180-day
25 exclusivity. If the first filer settles with the patent

1 holder, all subsequent ANDA filers are effectively blocked,
2 Your Honor -- the industry term is bottlenecked -- for entering
3 180 days after the first filer settlement entry date. And
4 that's what happened here, Your Honor. Solvay and Watson
5 reached an agreement on the 2015 entry date.

6 With one generic coming on, Solvay didn't have much
7 to lose from another. So Solvay offered the same date to Par
8 Paddock or based on the same date as Watson had with Par
9 Paddock. And that left Par Paddock with only two choices:
10 Accept Solvay's offer that was based on Watson's entry date or,
11 two, continue litigating the already three-year-old case
12 needing to win both in this court, Your Honor, and also at the
13 Federal Circuit.

14 And even assuming that Par Paddock could have pulled
15 off that litigation a year ago winning here and at the Federal
16 Circuit cleanly with no remand, Par Paddock under the pre-MMA
17 -- for the court reporter's benefit, that's M-M, those are M's
18 like Mary -- MMA amendments to Hatch-Waxman under the pre-MMA
19 Hatch-Waxman regime, Your Honor, Par Paddock would still have
20 to sit back and wait for Watson to enter and enjoy the 180-day
21 exclusivity.

22 Now, that's the only incentive that Congress provided
23 in this Hatch-Waxman regime for generics. So it doesn't make
24 sense that Par Paddock would have funded this litigation for
25 Watson to sit back and enjoy those benefits.

1 The Mova case that we cited at pages 18 through 19 of
2 our motion against the FTC, Your Honor, is very clear on this
3 point. One difficulty is that the 180-day exclusivity period
4 will seemingly always go to the first applicant no matter whose
5 suit satisfied the Court's decision. It seems odd to reward
6 the first applicant if some later applicant is the party that
7 actually prevailed in the patent infringement litigation.

8 And Congress recognizes statutory disincentive to
9 subsequent ANDA filers to continue to litigate. So Congress in
10 December 2003, Your Honor, changed the Hatch-Waxman Act; and
11 those are the MMA amendments that I have referred to here and
12 in our papers. Those do not apply here indisputably, Your
13 Honor.

14 Now, that's the regulatory background; and it helps
15 demonstrate why the date that Par Paddock obtained entry at the
16 same time as the first filer is a better result than even
17 Congress intended, Your Honor.

18 Now, if I could direct the Court's attention to the
19 chart of page 20 of our motion against the FTC. And if the
20 Court's interested, I have a freestanding copy here, Your
21 Honor.

22 THE COURT: All right.

23 MR. GRANNON: If I could approach.

24 And, again, this is at page 20 of our brief, Your
25 Honor. I have got copies here for counsel.

1 If you look at that chart, Your Honor, you can see
2 that in contrast to the other cases brought by the FTC the
3 second filer here enters at the same time as the first filer,
4 so there can't be any anti-competitive delay. In the first
5 line on the chart, Your Honor, in Schering-Plough, for example,
6 the second filer AHP settled for a date 28 months after the
7 first filer. And the FTC accordingly alleged that 28-month
8 period constituted anti-competitive delay.

9 In the second example in the chart, Your Honor, in
10 the Cephalon case Watson is the second filer there with an
11 entry date of six months after the first filers. Now, arguably
12 that six-month period should not be considered anti-competitive
13 delay because it results directly from the 180-day exclusivity
14 period. In any event, here, Your Honor, in this case there is
15 no daylight whatsoever between Par Paddock's entry date and the
16 first filer's. So there just isn't any basis to attribute any
17 competitive harm to Par Paddock's generic entry.

18 Now, the FTC tries to overcome this inability to
19 allege anti-competitive harm plausibly with three hypothetical
20 scenarios. In paragraph 94 of the second amended complaint,
21 Your Honor -- and that's quoted in full on page 22 of our
22 briefing at the FTC -- just very quickly, Your Honor, these
23 hypothetical allegations of competitive harm should really be
24 discounted. Schering-Plough, for example, quotes that rule
25 from the Supreme Court's Cal Dental decision which is at page

1 23 of our brief.

2 Furthermore, Your Honor, the Court we respectfully
3 suggest should be skeptical of these allegations because the
4 allegations of competitive harm in paragraph 94 against Par
5 Paddock are lifted verbatim, Your Honor, from paragraph 93
6 against Watson. All the FTC did was change the names, Your
7 Honor. And that type of boilerplate allegation we respectfully
8 suggest shows that the FTC has not accounted at all the
9 statutory distinction between first and subsequent ANDA filers
10 that Congress recognized that was obviously quite important.

11 Now, very briefly, the three allegations are
12 implausible. First, the FTC says that rather than settling Par
13 Paddock would launch at risk. But as a matter of law, Your
14 Honor, only Watson had the requisite FDA approval to launch at
15 risk. And the FTC effectively concedes this at paragraph 52 of
16 the second amended complaint where there it only alleges that
17 Watson had the requisite approval for launch.

18 Second, Your Honor, the FTC hypothesizes that Par
19 Paddock would continue litigating after a Watson settlement and
20 that Par Paddock had "ample financial incentive" to do so.
21 Now, this hypothetical goes right back to the point I just
22 made. Congress amended the Hatch-Waxman Act precisely for this
23 reason in December 2003. It recognized the statutory
24 disincentive to subsequent ANDA filers for continued litigation
25 after a first filer settlement and changed the law. So the

1 FTC's hypothetical allegation is really at loggerheads with
2 Congress's determination that second filers, subsequent filers
3 did not have such an incentive.

4 The final hypothetical, Your Honor, is that if Par
5 Paddock had not entered contemporaneous business transactions
6 that somehow Par Paddock would have gotten a better entry date.
7 And I think I'll just rest there by saying that this circuit's
8 authority is clear that this type of supposition is really
9 untenable, Your Honor.

10 So if the Court has no questions, Your Honor, I'll
11 just conclude by saying that a second filer coming in at the
12 same time as the first filer in a regulatory reality of
13 Hatch-Waxman, particularly before the MMA amendments of
14 December 2003, Your Honor, that's a pro competitive outcome
15 coming -- the second filer coming in at the same time as the
16 first filer.

17 Thank you, Your Honor.

18 THE COURT: All right, Mr. Grannon.

19 Is that it for the initial arguments for the
20 Defendants, Mr. Ryan?

21 MR. RYAN: Yes, it is, Your Honor.

22 THE COURT: Are you going first, Mr. Canfield?

23 MR. CANFIELD: I am, Your Honor. And I really have
24 only two points to make.

25 The first point is that while the private Plaintiffs

1 and the FTC actions are quite similar there are some obvious
2 and significant differences. The FTC's purpose in filing suit
3 was to get injunctive relief to benefit consumers by bringing
4 the price down as quickly as they can. They have asserted a
5 very narrow case and focused on the simple issue, relatively
6 straightforward issue of whether the settlement agreements in
7 the patent litigation are anti-competitive.

8 In the private case, private Plaintiff cases, we're
9 seeking damages. And while we agree that those settlement
10 agreements were anti-competitive, our allegations are much
11 broader. And they're much broader than the issue of sham
12 litigation. Our contention is that Solvay started a scheme
13 that was designed to delay generic competition on the market.
14 It began with the improper listing of AndroGel on the FTC's
15 Orange Book. The scheme continued through the filing of sham
16 litigation in order to improperly obtain the 30-month stay
17 under Hatch-Waxman, and it culminated in the settlement
18 agreements.

19 So we're not focused just on the settlement
20 agreements. We are not just focused on the sham litigation.
21 It's broader. We have also alleged that the generic Defendants
22 have entered into anti-competitive activity on their own by
23 agreeing among themselves that neither of them would continue
24 to attempt to market a generic version of AndroGel.

25 My second point deals with this patent litigation

1 that goes before the Court, and that litigation ended in at
2 least in my experience -- and the Defendants have asked us to
3 draw upon our experience -- my experience is that the
4 settlement in that case the way that case ended was very
5 unusual. The parties could have come to the Court and filed
6 stipulations of dismissal. The Watson -- in the Watson case,
7 they did that. In the Par Paddock case, they asked this Court
8 to enter a consent judgment.

9 And that consent judgment was a little bit weird. In
10 my experience, what the Defendant always says in litigation is
11 we don't have any liability. We'll settle with you, but we are
12 not going to admit we did anything wrong. In this consent
13 judgment, what happened is Par and Paddock came in and said
14 these are valid patents so we would be infringing if we went
15 and did what we were planning to do in this case. It's very
16 unusual.

17 They also asked the Court in the consent judgment to
18 make some findings about how they were acting in the public
19 interest which I don't usually see in cases that involve
20 private parties.

21 So why would they go to the trouble of doing all
22 that?

23 THE COURT: Noerr-Pennington.

24 MR. CANFIELD: That's exactly right, Your Honor.
25 They knew what they were doing. They wanted to make it appear

1 as if this -- what they had done was blessed by the Court, and
2 they wanted to be able to wave around that consent judgment and
3 try to convince people not to come after them.

4 We don't know what the lawyers told the Court at the
5 time that that consent judgment was entered. There apparently
6 were some telephone conferences. The minute orders and the
7 transcripts are under seal, so we haven't seen them. But I
8 doubt these Defendants told the Court that their agreements
9 were likely to be challenged as anti-competitive. I doubt they
10 submitted the agreements themselves to the Court. I doubt that
11 Solvay told Your Honor that they were paying more than a
12 hundred million dollars in order to avoid a finding one way or
13 another as to whether their patent was viable or not. I don't
14 think they told the Court all that.

15 And three years ago they were able to keep what they
16 did hidden from the light of day. If the Court will deny the
17 motions to dismiss, we'll have an opportunity to do now in this
18 case what this Court we believe was prevented from doing back
19 then which is to look at the substance of these consent -- this
20 consent judgment, look at what actually happened and make a
21 determination as to whether it was in the public interest and
22 whether it complied with federal antitrust laws.

23 That's all I have to say, Your Honor.

24 THE COURT: Thank you, Mr. Canfield.

25 MR. MEIER: Good afternoon, Your Honor. My name is

1 Markus Meier, and I am here on behalf of the Federal Trade
2 Commission.

3 THE COURT: Good afternoon, Mr. Meier.

4 MR. MEIER: May it please the Court.

5 I think I have got 30 minutes allocated by agreement
6 with the other Plaintiffs, and I'll ask Mr. Canfield to give me
7 the hook if I start running excessively beyond those 30
8 minutes. Let me give a quick overview of the -- how I intend
9 to proceed. Of course, I will be happy to answer any questions
10 that Your Honor has.

11 First question I'm going to try to answer is why is
12 the FTC here. It could very well be that Your Honor thought
13 you had gotten this case off your docket back in 2006 when the
14 parties settled their litigation, and suddenly here we are in
15 2010 right back in your court again talking about some of the
16 same issues that were being talked about back in 2006. I'd
17 like to give you a little bit of explanation about why that is.

18 Next I will address the Defendants' arguments
19 regarding the 11th Circuit precedent and why Your Honor should
20 not adopt their reading of that precedent.

21 Third, I would intend to address Par's Noerr
22 arguments. That's the argument through which Par's arguing
23 that your consent judgment immunizes their anti-competitive
24 conduct that's contained and embodied in the agreement that
25 they had entered into with Solvay, the payment agreements that

1 Your Honor made a reference to a moment ago.

2 And, fourth, time permitting, address Par's attacks
3 on the sufficiency of the FTC's complaint based on the Twombly
4 case and also the second filer status. And I'll try to explain
5 that a little bit more again if there's time permitting.

6 I think it's a fair question that might be on Your
7 Honor's mind to ask why is the FTC here to begin with. As I
8 said, you might well have thought this case ended back in
9 September 2006.

10 I'd like to be very clear upfront the FTC is not
11 anti-settlement. The FTC is not anti-patent. In fact, as we
12 have alleged in paragraph 101 of our complaint, patent
13 litigation can be and often is settled without raising any
14 antitrust issues. But Congress passed the Medicare
15 Modernization Act in 2003. Mr. Grannon referred to that as the
16 MMA, the Medicare Modernization Act. That's the same act that
17 created Medicare Part B which gives senior citizens the drug
18 benefit.

19 That act requires drug companies like the Defendants
20 here that enter into agreements with certain terms to file
21 those agreements with the Federal Trade Commission and the
22 Department of Justice. These agreements have to be filed
23 whether they occur in the context of litigation or not. It
24 doesn't matter whether it's litigated or not. The question is
25 what's the nature of the agreement and what's contained within

1 that agreement.

2 And Solvay, Watson and Par Paddock filed their
3 agreements with the FTC pursuant to their obligations under the
4 act. And Congress requires that the FTC review those. And it
5 is actually my office, the office I head, that does so. And we
6 have been reviewing those agreements since the requirement
7 kicked in in 2004. So that was two years before the settlement
8 occurred in this case we had started reviewing these types of
9 agreements as they have been filed with us.

10 Congress requires these filings under the Medicare
11 Modernization Act because of concerns that it had that branded
12 and generic companies are entering into anti-consumer
13 agreements that delay generic competition. And, of course,
14 this raises the cost of prescription drugs to individuals. It
15 raises the cost of prescription drugs to those who pay for it,
16 including government programs and employers.

17 And the very type of agreement we allege -- and we
18 set this forth in paragraphs 1 through 6 of our complaint and
19 actually all throughout our complaint -- the very type of
20 agreement that the Defendants entered into here was a payoff.
21 Solvay paid off Watson and Par to generic companies millions of
22 dollars to abandon their patent litigation, litigation that was
23 here before this Court, and to refrain from launching their own
24 lower-cost versions of a drug called AndroGel costing American
25 consumers millions of dollars. That's why we are here. These

1 factual allegations, of course, must be accepted as true for
2 the purposes of the motion to dismiss.

3 You have heard a little bit of discussion about the
4 Hatch-Waxman Act, and I'm not sure how familiar Your Honor is
5 with the Hatch-Waxman Act. It does loom large in the
6 background of this case --

7 THE COURT: Well, I think y'all all did a good job of
8 describing that. There's one sentence in the indirect
9 purchaser's complaint that I don't understand.

10 MR. MEIER: I can certainly take a shot at it.

11 THE COURT: You can explain it to me or somebody
12 else; but it's page 41 of the complaint, paragraph 88. And it
13 says: Under Hatch-Waxman their new dosage form exclusivity was
14 set to expire on February the 28th, 2003.

15 That I don't understand.

16 MR. MEIER: Your Honor, I will have to leave it to
17 the others to explain.

18 MR. GERSTEIN: Your Honor, I'm going to address that
19 during my whole presentation.

20 THE COURT: Fine, fine.

21 MR. MEIER: But we lay out a lot of the detail about
22 the Hatch-Waxman context in paragraph 17 through 23 of our
23 complaint. But I think it's worth just focusing on one aspect
24 of it. One aspect of the act was that Congress wanted to
25 increase the availability of generic drugs again because they

1 often reflected big cost savings to everybody who pays for
2 prescription drugs in the United States. And it did so by
3 creating a special set of procedures to facilitate patent
4 challenges. These are often referred to as paragraph 4
5 filings. You may have seen that.

6 And the very settlement -- the very litigation that
7 was involved before Your Honor was in paragraph 4 involving
8 paragraph 4 of the Hatch-Waxman Act. These were the procedures
9 that Watson and Par, the generic companies, had invoked in
10 challenging Solvay's AndroGel formulation patents giving rise
11 to the lawsuit that is before Your Honor.

12 And as we allege in paragraphs 24 through 29,
13 Congress recognized that there was significant savings to
14 consumers and our health care system from generic drugs. And
15 as we allege in paragraph 30, Congress also recognized that
16 some patents on some drugs aren't really all that. Thus,
17 Congress created financial incentives for generic companies to
18 go looking for branded patents that may not really be valid or
19 to try to invent around patents that don't really have much
20 scope, don't cover very much and that are easily circumvented
21 by inventing around them.

22 The point of the paragraph 4 filing that Congress
23 created was to facilitate generic entry prior to patent
24 expiration. It's an understanding that it's sometimes possible
25 for generics to get into the market before the patents expire.

1 But according to Defendants, absent proof of sham litigation a
2 brand can use its monopoly profits to purchase generic
3 exclusion right up to the point that the patent expires.
4 Patent expires in 2020. They could have bought protection
5 right up to 2020 so that anybody could enter only after the
6 patent had expired.

7 And under the Defendant's standard, even a trivial
8 patent, one that's likely to be invalid or not infringed, gives
9 the patentee the right to buy protection from competition from
10 as many other competitors as it wants for as much money as it
11 wants to spend right up to the expiration of the patent term so
12 long as the infringement claim is not a sham.

13 So let's turn a little bit to the 11th Circuit
14 precedent. Obviously, the 11th Circuit decisions in Valley
15 Drug, Schering and Andrx are controlling precedent. That's
16 beyond dispute. It was interesting that Mr. Ryan never
17 actually spoke about Valley Drug. He talked about Schering.
18 But actually all of those are controlling precedent for this
19 Court.

20 The real issue is how to read those decisions. And
21 Mr. Ryan made much of the fact, and it is true, that the FTC
22 has read the 11th Circuit's decisions in other cases
23 differently than the way I'm advocating for today, Your Honor.
24 That is absolutely true. We acknowledge that that we took in
25 our position in our appeal to the Supreme Court that the 11th

1 Circuit appeared to adopt and under the patent term standard.
2 Frankly, if you spend time looking at that, some courts and
3 other writings on this, the 11th Circuit decisions have been
4 read differently by many people, not just the FTC. But, of
5 course, the only reading that really matters here, Your Honor,
6 is the reading that you give to these decisions.

7 According to Defendants, the controlling 11th Circuit
8 precedent absent sham infringement allegations or fraud on the
9 Patent Office in procuring a patent, a settlement litigation is
10 immune from antitrust laws so long as it does not delay entry
11 -- and this is their words in their motion -- beyond the end of
12 the patent life. In effect, what Defendants are saying is that
13 a patent holder like Solvay is entitled to use its monopoly
14 profits to buy protection from competition until the patent
15 expires and that Solvay can do this regardless of the strength
16 of its patent. It's saying don't look at the strength of the
17 patent, we can do this -- as long as the patent runs 'til 2020,
18 we can do it to 2020.

19 Under Defendants' end of the patent term standard
20 which even Mr. Sunshine acknowledges a very narrow exception,
21 it makes no difference whether the patent is likely to be found
22 invalid. It makes no difference whether Watson and Par
23 Paddock's generic products are likely to be found not to have
24 infringed Solvay's patents.

25 Indeed, under the Defendants' standard -- this is in

1 their motion to dismiss at page 17 -- this Court need not
2 consider the complaint's allegations that Solvay's patents
3 were, quote, unlikely to prevent generic entry when determining
4 the scope of the exclusionary potential of patent as we have
5 alleged in paragraphs 86 through 92. That's where we allege
6 that it was unlikely that Solvay's patents would have kept the
7 generics out. And it's alleged in quite a bit of detail, Your
8 Honor. And I'd again refer to paragraphs 86 through 92.

9 THE COURT: Well, now, Mr. Meier, would you agree
10 that that's a little more lenient standard than the no
11 reasonable litigant would expect to succeed on the merits of
12 the case?

13 MR. MEIER: Lenient in whose direction?

14 THE COURT: In yours, in your direction.

15 MR. MEIER: Let me see if I can understand. Maybe I
16 could hear that again.

17 THE COURT: I think you're arguing for a more
18 forgiving standard for sham litigation than the Supreme Court
19 adopted in the whatever it is, the REM or whatever --

20 MR. MEIER: No, I'm actually not at all trying to
21 argue for what the Supreme Court meant when it talked about
22 sham. So if that's how Your Honor understood the arguments so
23 far, I'm not addressing myself at all to what the sham standard
24 is. I will be addressing myself and I am trying to address
25 myself to what the 11th Circuit has said what you do in a case

1 like this when you are confronted with an agreement of the
2 nature that the Defendants have entered into.

3 THE COURT: So you are saying that some standard
4 below sham litigation is the effective standard in the 11th
5 Circuit?

6 MR. MEIER: Yes, Your Honor. I'm saying --

7 THE COURT: That's what I thought you were saying.

8 MR. MEIER: In fact, let's turn right to it. Let's
9 look exactly at the plain language of the 11th Circuit because
10 the 11th Circuit, if you go looking for it, Your Honor, you are
11 not going to find a lot of discussion about the sham standard.
12 I grant you you will find that in some other circuits, and
13 Mr. Ryan's already made reference to that. You will find that
14 in the 2nd Circuit's decision. You will find that in the
15 Federal Circuit's decision. They used the language sham
16 standard. It's very clear.

17 And so when a court wants that to be the standard,
18 courts have no problem saying that's the standard. But that's
19 not what the 11th Circuit did. In fact, let's just take a
20 quick look at this.

21 The place to start is, of course, with Valley Drug
22 because that was the first case of this type that was brought
23 here in the 11th Circuit and which Mr. Ryan never mentioned.
24 And there the language is, "Plaintiffs' arguments require
25 consideration of the scope of the exclusionary potential of the

1 patent, the extent to which these provisions of the agreements
2 exceed the scope and the anti-competitive effects thereof."
3 The word sham doesn't show up in there. It talks about the
4 scope of the exclusionary potential of the patent, Valley Drug
5 at 1312.

6 In Schering-Plough -- this was a case that the FTC
7 brought and we lost here in the 11th Circuit -- the court there
8 says, "We are bound by our decision in Valley Drug. Therefore,
9 in line with Valley Drug we think the proper analysis of
10 antitrust liability requires an examination of, one, the scope
11 of the exclusionary potential of the patent; two, the extent to
12 which the agreements exceed that scope; and, three, the
13 resulting anti-competitive effects."

14 That's at 1065 through 66. Again, the word sham
15 doesn't appear. What does appear --

16 THE COURT: Well, it doesn't appear because sham
17 litigation as I understand it is a narrow exception to the
18 immunity that otherwise comes if the exclusionary conduct is
19 within the scope of the patent. That's the way I understand
20 it, which is two different things.

21 MR. MEIER: Right. But what I'm focusing on is what
22 does that mean, the exclusionary scope of the patent. Are
23 those two different things?

24 And I think Your Honor is saying, yes, they are two
25 different things. And if that's the case, Your Honor, I

1 absolutely agree. They are conflating them. They are saying
2 they are the same thing. I am saying the exclusionary scope of
3 the patent is something different than the sham standard.
4 That's exactly what we're saying.

5 And so what do the plain words of the scope of the
6 exclusionary potential of patent mean?

7 It means you take a look at the patent. It can mean
8 taking a look at what does this patent cover, what's the
9 language of the patent, what does the patent cover, what
10 property rights do they have as a result of this patent and how
11 does that compare to what the generic companies are proposing
12 to do. It requires some consideration of the validity of that
13 patent and some consideration of infringement.

14 THE COURT: I think that's where the Defendants and
15 you differ, Mr. Meier.

16 MR. MEIER: Exactly. That's exactly right, Your
17 Honor. We differ because they say sham standard, that's it,
18 you put the blinders on, you don't look at the patent. And we
19 are saying, well, wait a minute, that's not what the 11th
20 Circuit said. I have just read it from Valley Drug. I have
21 just read it from Schering. And there's the third case, the
22 last one they brought that came here, Andrx v. Elan, which is
23 the most recent. And, not surprisingly, it's exactly the same
24 language: To prevail on a claim that a patent infringement
25 settlement agreement violates Section 1 of the Sherman Act, a

1 Plaintiff must prove the scope of the exclusionary potential of
2 the patent.

3 And not only is Andrx the most recent case here in
4 the 11th Circuit applying the standard, but notably the 11th
5 Circuit said that the District Court improperly dismissed the
6 case on the pleadings. The 11th Circuit applied the standard
7 that we're advocating for that we think the 11th Circuit said
8 that we're talking about today and held that the Plaintiffs'
9 challenge to an allegedly anti-competitive patent settlement
10 should proceed past the pleadings. It was improper --

11 THE COURT: Wasn't there something having to do with
12 the second filing rule where they extended the 180-day period
13 or something like that in that case?

14 MR. MEIER: There were other factors, and there are
15 other facts in that case that are not at play in this case. I
16 will grant you that, Your Honor.

17 But the bottom line is if the 11th Circuit had
18 intended to adopt a sham standard as Defendants advocate, it
19 could have said so. Instead, it adopted a standard that calls
20 for an examination of the scope of the exclusionary potential
21 of patent. And I invite the Court to think about what does
22 that mean.

23 THE COURT: You are saying that that means that I
24 look not only at the claims of the patent but the validity of
25 the patent?

1 MR. MEIER: At least some consideration of the
2 validity and some consideration as to whether a Defendant's
3 products would infringe that patent. Again, how much does that
4 patent really cover? Does it cover a very narrow thing that
5 it's easy for somebody to get from Point A to Point B by just
6 walking around that piece of property? Or do you have to
7 really go across that piece of property to get from Point A to
8 Point B?

9 THE COURT: Well, that part seems pretty easy to me
10 in this context because in order to get the abbreviated new
11 drug application approved you have got to show that the
12 generic's product, I believe, is the bioequivalent of the
13 branded product. That's pretty good proof or pretty good
14 indication that the two are the same and that if the patent
15 covers one it's probably going to cover the other.

16 MR. MEIER: Well, you might think that, Your Honor;
17 but you have to draw a distinction between what's known as a
18 compound patent and what's known as a formulation patent.
19 Compound patent is the aspect of the drug that makes the drug
20 the drug. Let's say Prozac. That's always the generic name,
21 fluoxetine. Fluoxetine is the compound. Anybody that wants to
22 practice the compound patent, it would be absolutely
23 coextensive.

24 But what's at issue in this case is not the compound.
25 It's not testosterone. That's the compound in AndroGel,

1 testosterone. It's been synthesized, and it's been patented a
2 long time ago. Those patents are long gone. There are no
3 patents on that anymore.

4 And this product involved a gel formulation. You can
5 take testosterone gel and put it on your body and get
6 testosterone if you have low testosterone if you are a male.
7 Gel is also long known about. Those patents are long gone.

8 It's a formulation patent that says you mix a certain
9 amount of testosterone, a certain amount of gel and certain
10 other ingredients. Well, somebody else can take testosterone
11 and gel, tweak the ingredients a little bit and get roughly the
12 same thing, get something that they can go to the FDA with and
13 say this is bioequivalent. But it doesn't touch on Solvay's
14 property because Solvay doesn't own a patent on testosterone
15 and Solvay doesn't own a patent on gel. It owns a formulation
16 patent.

17 And that often happens in a lot of these cases, Your
18 Honor. So when you go back and read some of these cases, you
19 have to look at the difference. A lot of these cases involve
20 formulation patents, things like, for example, what gives a
21 24-hour-release pill its 24-hour-release profile. Well,
22 there's different technologies that can be used to do that.

23 And those are formulation patents. And generic
24 companies can come a ways to invent around that particular
25 formulation and still go to the FDA and get approval as a

1 bioequivalent because what bioequivalency means is it means it
2 works the same way in the body. It gets the same uptake and
3 works the same way in the body; and it's the same active
4 pharmaceutical ingredient, the same dosage form, the same
5 strength. But it does not mean it's exactly the same mixture.

6 We also cite -- and I will go through this very
7 quickly -- in the FTC's briefs that Defendants' reading of the
8 11th Circuit precedence would conflict with Supreme Court law.
9 The Gypsum case and the Glaxo case, in both Glaxo and Gypsum
10 the government like we are here today alleged that the
11 Defendants had entered into anti-competitive agreements that
12 violated the antitrust laws. The Defendants in those cases did
13 not deny that they've entered the agreements, just as these
14 Defendants don't deny they've entered the agreements, but
15 rather as the Defendants do here they claimed the agreements
16 were merely the legitimate exercise of patent rights.

17 I will grant you Gypsum and Glaxo had nothing to do
18 with the exclusion --

19 THE COURT: You are kind of asking me to go out on a
20 limb to ignore three 11th Circuit cases and go back and follow
21 a 50-year-old Supreme Court case, Mr. Meier.

22 MR. MEIER: I was terribly unclear if that's what you
23 thought I was asking, Your Honor. I am saying read those 11th
24 Circuit cases consistent with the Supreme Court cases, not
25 ignore the 11th Circuit. I'm saying absolutely you are bound

1 to follow the 11th Circuit precedent. There is no question
2 about that. And I have gone through that precedent and shown
3 you how that precedent talks about the scope of the
4 exclusionary area of the patents. And now I'm saying, by the
5 way, there's some Supreme Court cases that say in government
6 cases where we're bringing an antitrust case and there's a
7 patent at issue you go look behind the patent. You lift the
8 hood up, and you take a look at it. So I'm saying it --

9 THE COURT: Now, Schering-Plough was an FTC case,
10 wasn't it?

11 MR. MEIER: It was, Your Honor. It was.

12 So I'm saying read these two consistently because I
13 don't want you to go against the Supreme Court. I don't want
14 you to go against the 11th Circuit either.

15 THE COURT: All right, Mr. Meier.

16 MR. MEIER: And Defendants' reading of the 11th
17 Circuit cases also conflict, by the way, with the way other
18 people have read it. And perhaps most important for this Court
19 and useful to this Court is to take a look at what the District
20 Court did in the Southern District of Florida in the Terazosin
21 case. That was remanded from the 11th Circuit. That's the
22 remand from the Valley Drug case in the 11th Circuit. They
23 sent it back to a judge like yourself down in Florida.

24 And what did the District Court do in Florida?

25 It held on summary judgment that a patentee exceeded

1 the protection of four to five patents, and it violated the
2 antitrust laws by paying competitors not to compete. They said
3 look at the exclusionary scope of the patent. District Court,
4 you didn't do that. Now do it.

5 District Court went and did it in a case very similar
6 to this one. And notably in that case the Florida District
7 Court explicitly decided that the underlying patent case was
8 not a sham. It expressly said that that was not sham
9 litigation, but I'm going to take a look at the patent because
10 that's what the 11th Circuit told me to do. When I take a look
11 at the patent on summary judgment, they found that it exceeded
12 -- the agreement exceeded the protection afforded by the
13 patent.

14 And, interestingly, Defendants themselves have argued
15 that this case should be transferred to Your Honor for this
16 very reason. As you know, we brought this case originally in
17 California. The Defendants filed a transfer motion. Page 14
18 through 15 this is what they said. "Transfer is also" -- this
19 is what they said to Judge Pfaelzer in California -- "Transfer
20 is also warranted because of the substantial savings in
21 judicial resources that will result from the Northern District
22 of Georgia's familiarity with the underlying patent
23 litigation."

24 Why would they tell her that your familiarity with
25 patent litigation is a reason to come here and now they are

1 telling you, But don't look at the patent, it's the sham
2 standard?

3 In their transfer reply brief, "The court that
4 resolves the government's antitrust allegations must weigh the
5 patent merits." But now they are telling you don't look at the
6 patent. It's the sham standard.

7 And Mr. Ryan himself at the transfer hearing before
8 Judge Pfaelzer, page 14 of the transcript, told her, "Now, the
9 patent merits are critical to our venue motion because this is
10 exactly the issue that was tried, that was litigated in front
11 of Judge Thrash for three years, that is to say, what are the
12 merits of the patent."

13 And, finally, Mr. Ryan at the hearing before the
14 Multidistrict Litigation Panel where a lot of the private
15 Plaintiffs were, at page 8 and 9 of that transcript said, "But
16 I must say in all deference to Judge Thrash and his schedule
17 there were three years of patent litigation in front of Judge
18 Thrash that's now going to have to be repeated. There are
19 substantial efficiencies by having Judge Thrash oversee these
20 cases. He is familiar with the issues. And don't -- that's
21 not just me. That is part of the rationale of Judge Pfaelzer's
22 decision when she sent the FTC's case here."

23 Now Mr. Ryan and Defendants are saying, Put on the
24 blinders, don't look at the patent, it's a sham standard.

25 So to summarize, instead of reading the 11th Circuit

1 court's precedent as Defendants argue, Your Honor should look
2 at the plain language of those precedents, read them consistent
3 with Supreme Court law, apply them as the Southern District of
4 Florida did on remand in a similar type of case and as the
5 Defendants themselves argued when they tried to get this case
6 and successfully got this case transferred to this court.
7 Under this reading of the 11th Circuit precedent, the FTC's
8 complaint clearly states a claim as set in paragraphs 86
9 through 92.

10 Now, again, I'm not sure how I'm doing on time. What
11 kind of patent inquiry, it might be interesting to talk a
12 little bit about what kind of patent inquiry would the 11th
13 Circuit precedence require Your Honor to undertake. And,
14 again, I'd refer to the Terazosin court's decision. That's the
15 Southern District of Florida on remand from the 11th Circuit in
16 Valley Drug. It was faced with the very same question. And
17 here's what the 11th Circuit instructed the court to do in
18 Valley Drug on the remand. It's a bit of a long quote, but I
19 think it's worth reading the whole thing. This is on page
20 1312:

21 "The appropriate analysis on remand will likely
22 require an identification of the protection afforded by the
23 patents and the relevant law in consideration of the extent to
24 which the agreements reflect a reasonable implementation of
25 these. Appellants, for example, contend that certain

1 provisions of the Geneva Agreements are analogous to a
2 consensual preliminary injunction and a stay of judgment
3 pending appeal. To evaluate this claim, the provisions of this
4 agreement should be compared to the protections afforded by a
5 preliminary injunction and stay mechanisms and considered in
6 light of the likelihood of an Abbott obtaining such
7 protections" -- Abbott was the brand company -- "what was the
8 likelihood that Abbott could have gotten an injunction,
9 preliminary injunction, what was the likelihood that Abbott
10 could have kept the generics out, and compare that to what they
11 did under the agreement. But that requires taking a look at
12 the patent."

13 And on remand the District Court did just that. It
14 considered the likelihood of the patentees' success as seen at
15 the time, not trying to do a full-blown patent trial at the end
16 but as seen at the time of the agreement what was the
17 likelihood of the patentees' success. And the Florida District
18 Court undertook its analysis without conducting a full-blown
19 patent trial. Instead, it did it on a summary judgment record;
20 and the record included briefs with citations to the patent
21 record and a couple of expert reports.

22 So what would this mean for this court if you deny
23 the motion to dismiss as we respectfully request?

24 It mostly would mean briefing and argument on papers,
25 including exhibits from the patent record at the time. It

1 might also mean limited testimony from experts. But it would
2 not necessarily mean engaging in a full-blown, after-the-fact
3 patent trial.

4 Now, I'm anticipating what one of the arguments that
5 Defendants will make as they come back up here in rebuttal.
6 And I'm certain -- I'm confident that they will tell you the
7 Terazosin case shouldn't really be paid that much attention to,
8 the Florida case where the judge faced the same situation you
9 do because it involved what's known as an interim settlement as
10 opposed to a final settlement. What that means, there the
11 parties' agreements didn't resolve the entire litigation. It
12 really was more of a generic agreeing not to enter during the
13 pendency of the litigation. It was like a preliminary
14 injunction perhaps pending the outcome of the court decision.

15 But I believe if you hear that argument, Your Honor,
16 it's not persuasive if you look carefully at the 11th Circuit
17 decisions because, first of all, in Valley Drug itself the
18 District Court was analyzing two agreements. As here there was
19 a branded company Abbott, there was a generic company Geneva
20 and another generic company called Zenith. And Abbott entered
21 an agreement with Geneva, and Abbott entered an agreement with
22 Zenith. The Abbott agreement with Geneva was interim. The
23 Abbott agreement with Zenith was a final settlement. They were
24 both in play.

25 And, truthfully, the 11th Circuit applied the same

1 standard to both the interim settlement and the final
2 settlement. And it talks throughout the decision about the
3 agreements, not about the interim agreement and not about the
4 final agreement, but it talks about the agreements. And when
5 the 11th Circuit provided the District Court with the
6 instructions on remand, it again referred to both the final and
7 interim settlement agreements in the plural: "The appropriate
8 analysis on remand will likely require an identification of the
9 protection afforded by the patents and the relevant law in
10 consideration of the extent to which the agreements reflect a
11 reasonable implementation of these."

12 That's at 1312.

13 And the court -- the 11th Circuit applied the same
14 legal standard in that third case which we haven't talked that
15 much about, the Andrx v. Elan case, even though the agreement
16 in that case was a final settlement. So I don't think this
17 distinction between interim settlements and final settlements
18 holds water in the context of his motion to dismiss and what
19 we're talking about here today.

20 Let me take a look back. I am getting pretty close
21 to the end. Let me just real quickly turn to Noerr, Par's
22 Noerr argument. And what Par is saying in that case is that
23 its private agreements with Solvay not to compete are entitled
24 antitrust immunity because of the action of Your Honor in
25 entering the consent judgment. What they're saying is, Your

1 Honor, when you entered this six-page consent judgment which
2 Mr. Gidley said they subjected themselves to the consent
3 judgment, but I think they proposed it to you, you basically
4 blessed everything that's in their agreements in which they
5 settled.

6 Now, this was signed on September the 15th by Your
7 Honor. These agreements were entered on September 13th, a
8 couple days before. And I doubt -- there's absolutely no
9 evidence that I found in the record that they ever presented
10 these agreements to you so you could see what was really going
11 on here. According to Par, this is the source of the restraint
12 on competition, not this.

13 Okay. Since I'm past my time, Your Honor, I am going
14 to go ahead and sit down unless you have any other questions.

15 THE COURT: All right, Mr. Meier.

16 All right. Well, let's take a ten-minute break.
17 Court's in recess for ten minutes.

18 (A short recess was taken.)

19 MR. GERSTEIN: Good afternoon, Your Honor.

20 THE COURT: Yes, sir.

21 MR. GERSTEIN: I'm Bruce Gerstein, Garwin, Gerstein &
22 Fisher from New York. I am speaking on behalf of the direct
23 purchaser Plaintiffs. I represent the Louisiana Wholesale Drug
24 Company.

25 THE COURT: All right. Mr. Gerstein, the Plaintiffs

1 have 25 minutes of your time left.

2 MR. GERSTEIN: Okay, Your Honor.

3 Judge, during the course of the FTC's argument, you
4 asked the question which I think is a very, very important
5 question; and that is you referred, I think, to the indirect
6 purchaser's complaint and you asked what was that about, the
7 NCE exclusivity and the February 3rd, 2003, date. And it's not
8 only part of their case, but it's part of all the cases. And I
9 think it's important to understand that what that's about is
10 Hatch-Waxman.

11 THE COURT: Well, don't waste your time on that if
12 you don't think it merits it, Mr. Gerstein. I was curious as
13 to what it meant.

14 MR. GERSTEIN: No, I think it's critical to our
15 claim; and that's why I wanted to explain it in that context
16 because I wanted to explain what's going on here so the Court
17 could understand two statutory regimes going on at the same
18 time. Defendants only talked about the patent which Your Honor
19 had considered in prior litigation, and they described it. We
20 weren't party to it, but they described it.

21 But there's other factors going on, and that's
22 Hatch-Waxman. Independently of the patent, the Hatch-Waxman
23 law provides that the branded company who files an NDA with
24 them gets a certain amount of exclusivity. It can range from
25 three to five years. In this case, it was a five-year

1 exclusivity that was ending in February 2003. What that
2 exclusivity means is that the FDA will not even accept
3 applications from generics until that exclusivity period ended.
4 So you have to think about that that automatically independent
5 of the patent there is a statutory regime that's giving the
6 branded company --

7 THE COURT: So even if you don't have a patent.

8 MR. GERSTEIN: Even if you don't have a patent. And
9 that's very, very important because there's other provisions we
10 referred to in our briefing and in the complaint which can
11 extend that out. And this is the crux of our scheme claim; but
12 independently it's an element of an antitrust violation as well
13 as part of a larger scheme that you can extend it if, in fact,
14 you file a patent in what's called the Orange Book which -- and
15 these are very specific requirements that --

16 THE COURT: Yeah, I understand that. I got that.
17 Y'all did a good job explaining that.

18 MR. GERSTEIN: Okay. But if you file your patent in
19 the Orange Book and meet the standards and the standards are
20 both substantive and timewise -- and I am going to get to that
21 in a second -- you automatically can extend your exclusivity
22 for up to 30 more months. That means that as a result of doing
23 that you have effectively extended your monopoly even if you
24 didn't have a patent.

25 THE COURT: I thought you had to have a patent to get

1 the 30 months.

2 MR. GERSTEIN: You have to have a patent. You're
3 extended for 30 months if you have a patent. I'm sorry. I
4 misspoke.

5 But the two requirements that you have to deal with
6 is one is having filed properly and timely a patent in the
7 Orange Book, and two is bring a lawsuit within 45 days. And,
8 specifically, if you don't do either one of those, you don't
9 get the 30 months. That is critical to our claim because we
10 have shown and we've done in detail why the initial Orange Book
11 listing on its face was improper.

12 Critical -- and I just want to go back to this -- is
13 under the law the filing in the Orange Book with the FDA is not
14 Noerr protected. It's not petitioning. There's no PRE
15 standard. It's either improper or not. There's a standard
16 that you have.

17 Now, as to what we have shown is Defendants
18 acknowledge specifically that when they filed their patent with
19 the Orange Book it was mistaken on its face. As to claims 1
20 through 30, they had the wrong range for sodium hydroxide.

21 And what did they do?

22 They went back to the Patent Office to try to get the
23 certificate of correction. There's only two problems with
24 that. One is if you don't file a patent at that point and wait
25 to get the certificate of correction which you could then argue

1 claims the patent -- the drug on its face, the approved drug on
2 its face, it doesn't apply to any previously filed ANDAs. But
3 if you basically file at that time so that you meet the first
4 element of the requirements to get the 30-month stay, on its
5 face it doesn't meet the substantive requirements. So they had
6 a problem.

7 And what did they do?

8 They have gone back and labeled the problem a
9 ministerial error. And I submit to Your Honor I'm not going to
10 argue with them. We put in our briefs why it wasn't. But it
11 doesn't matter. It's no different, for example, if you have a
12 Statute of Limitations and you miscounted on the clock and you
13 filed the next day. You made an error. There is nothing in
14 the specific statute that says errors can be forgiven. There
15 is a requirement, and those requirements have to be met to get
16 the 30-month stay.

17 We have alleged specifically that they had a bind
18 because they knew that if, in fact, they waited to get their
19 certificate of correction the next time they could actually
20 file a lawsuit would be when the generics actually entered the
21 market. And they say in their papers, so what. Then we could
22 have brought a suit -- you know, we could have brought a suit
23 against them; and we would have had in their point not a sham
24 litigation. They argue even if it's a weak litigation it
25 doesn't matter. But it does matter all the same.

1 Why?

2 Because if you have a 30-month stay, it's automatic.
3 If you have to wait 'til specifically generics enter the
4 market, you have to go for an injunction because -- and that
5 means you have to establish to do exactly what you got from the
6 30-month stay. You'd have to convince this Court of the
7 likelihood of success and irreparable harm to actually get the
8 stay. They push all that aside for the antitrust.

9 What we have alleged principally in our case as part
10 of the scheme is that before they got to the agreements context
11 they went out and manipulated the Hatch-Waxman statutory scheme
12 to get their 30 months additional which harmed the consumers
13 and competition. And that is generally the crux of our case.

14 I've heard Noerr-Pennington, Noerr-Pennington,
15 Noerr-Pennington. That applies specifically only as to sham
16 lawsuits. It doesn't apply to the Orange Book listing and
17 whether or not the Orange Book listing is improper. And we
18 have made allegations specifically as to why it wasn't, and
19 much of it is conceded.

20 There's a reason you haven't heard anything about the
21 Orange Book listing in their opening. They don't want to
22 address it. They want to conflate this only as to the sham.
23 But if you are looking at an antitrust violation, did they do
24 something that manipulates the government process, in a way
25 they're giving them the ability to exclude competition where

1 they otherwise couldn't. Now, that is the beginning; but it
2 just shows the context of where they were in the agreement.
3 And as far as we know, none of that was before the Court.

4 So that is if you are looking generally in the
5 allegations, that is the crux of our scheme claim. The fact of
6 the matter is the generics have argued, well, they haven't
7 alleged the Orange Book listing or sham litigation or anything
8 improper up to that point against us. We are not bringing a
9 specific claim against them for those independent acts. We are
10 bringing a claim because the generics by entering into
11 agreements joined the scheme by agreeing at that point to allow
12 Solvay to extend out its monopoly. And that's what we have
13 alleged specifically in the complaint.

14 So if you look at the overall facts, they are sitting
15 there saying, Judge, it was a mistake, forgive us. But that's
16 not what is allowed under Hatch-Waxman. They had a problem,
17 and the problem was we couldn't properly file the Orange Book
18 on the day that we filed it. And if we waited, it would not be
19 applicable to the ANDAs filing by the generics that were filed
20 prior to the date that they got a certificate of correction.
21 They're in a box. And what they do which is exactly what's
22 wrong under the antitrust laws, they want to self-help. They
23 didn't want to use the rest of the regime that was available to
24 them under the patent law, wait for the generics to come to
25 markets, go out and seek an injunction to try to exclude them

1 because that would be a very different position.

2 That is the crux of our Orange Book listing, and I
3 refer the Court to our briefs because we have tried to cover as
4 much detail as we can what was the substantive and procedural
5 basis.

6 I'd like to turn again because I think it's as
7 important to the 11th Circuit cases. I know the Court has
8 raised issues about it. The only thing I'd like to suggest to
9 the Court is that -- and I know that this is repeating what
10 Mr. Meier said in general, but I'd like to go a little bit more
11 specific -- is that there's been a lot of things said about
12 what the case law says. But it's very, very important to read
13 it and read it clearly. If the Court would indulge me, I have
14 made copies of Schering-Plough because I want to just
15 specifically refer to certain language and I have yellowed it.
16 And I have copies for everybody.

17 THE COURT: That's fine. I have got a copy up here.

18 MR. GERSTEIN: I appreciate that. It's easier for me
19 because of the short time.

20 Judge, first of all, everything is in context. So
21 I'd like to say it from my perspective having read it, as a
22 matter of fact, having really studied it in the last number of
23 weeks again because I have argued this on a number of
24 occasions, but I'd like to start with Schering and then go back
25 to Valley Drug. If you look at Schering in context, it's very

1 important to understand what has not been said that this was
2 after a trial. This was not at the motion-to-dismiss stage.
3 It was not a motion-for-summary-judgment stage. It was after
4 the administrative law judge actually tried the case. And if
5 you read that in context, I believe you'll see that what
6 Mr. Meier is suggesting is absolutely clear as a bell from the
7 decisions.

8 For example, the court where I have on page 7 in the
9 yellow, it notices specifically that the ALJ which specifically
10 evaluated the strength of the patent, that was a finding. If
11 you turn to page 9 in the quoted passage, it specifically shows
12 when he made his findings that he determined what they call the
13 exclusionary power of the patent after considering the evidence
14 by the Defendants versus the clear lack of evidence put in by
15 the Federal Trade Commission. Matter of fact, they criticize
16 the Federal Trade Commission because what they said was they
17 cavalierly dismissed their requirement to do it. But look
18 where I underlined it. It said without any evidence to the
19 contrary there is a presumption that the '743 patent is valid.

20 I also would like to refer to the Court because I
21 think it's very important, you made a statement in your
22 comments to -- I believe to Mr. Meier earlier about whether he
23 is suggesting that the 11th Circuit was suggesting or opining
24 that it was a lower standard than a sham standard in connection
25 with reverse payment cases. And if you look at page 8, the

1 Court is quoting from Judge Posner who was sitting at that time
2 as a District Court judge by designation in the Sahi case. And
3 look at the language. It's almost the identical language that
4 you had suggested would be a lesser standard.

5 It says: Suppose a seller obtains a patent that it
6 knows is almost certainly invalid that is almost certain not to
7 survive the judicial challenge. As soon as its competitors
8 have settled the suit by licensing them to use its patent in
9 exchange for the agreement not to sell the patented product for
10 less than the price specified in the license, in such a case
11 the patent is sued and the settlement would be devices for
12 fixing prices in violation of the antitrust law.

13 That's not a sham standard. As soon as it says
14 almost certainly, that's not a sham standard. It's something
15 less. It's evaluating exactly what Your Honor was positing.
16 And they were just using this as an illustrative statement.
17 But if you think about what we're arguing we're fighting over
18 what does it mean when it says exclusionary power of the
19 patent? Does it just mean the nominal term as they are
20 suggesting that a patent holder has the absolute right to
21 exclude up to the point of determining invalidity? Or is the
22 Court actually saying you have to give credence to the validity
23 of the patent holder or what the evidence is and weigh that?
24 You have to give credence to what the Court is really saying I
25 believe, and it emphasizes exactly?

1 What's really going on here? Is this really a
2 settlement of patent litigation, or is this something else?

3 Now, the other points I was making 'cause this is
4 after trial and I know that the FTC disagrees with this -- I
5 have a private case, and I disagree with this -- but the
6 administrative law judge also specifically found on the
7 evidence that the moneys that were alleged to be the reverse
8 payment to pay off the generic not to come from market had
9 nothing to do with that. It had to do with separate license
10 fees which were fair. That was the finding of the Court. That
11 was binding. That was what was reviewed.

12 So they're actually finding in this case that you
13 have a settlement where you have payments separate and apart to
14 pay for licenses and a settlement of the patent suit for a
15 lesser term. Nobody argues specifically if you just are
16 negotiating on the term that that wouldn't be -- that would
17 create antitrust problems. It's when it happens where the
18 alleged wronged party is being paid by the alleged wrongdoer,
19 and that's where the problem comes in.

20 THE COURT: So you're saying then that if the
21 Defendants in this case had simply entered into an agreement
22 that the generics could have a license to sell generic AndroGel
23 in 2015, no money changed hands --

24 MR. GERSTEIN: I said if they only settled for the
25 term, yes, nothing else. But if, in fact, the license is a

1 reverse payment, those are always issues that you have. But
2 if, in fact, they just negotiated simplest case, we will agree
3 not to come on until sometime less and nothing else more that
4 the branded did not pay off the generic any other way, that is
5 a means of settling patent suits all the time. That's what
6 they do. And from what I understand, they do not come under
7 antitrust --

8 THE COURT: So you are saying it's the payments that
9 made --

10 MR. GERSTEIN: It's the payments that make
11 everything. And if you think of the logic, it's what they call
12 reverse payments because the reverse payments are being made by
13 the alleged wrongdoer.

14 Now, I am going to go far afield for one second
15 because Defendants always said, well, that's because it's
16 created by the asymmetrical negotiating power. That's what
17 they said in their briefs. The fact of the matter is it's the
18 branded company that creates an asymmetrical negotiating power.

19 If you go back to my explanation at the beginning of
20 the 30-month stay in the Orange Book listing, if the branded
21 does not want to get that asymmetrical negotiating power that
22 the suit is brought before the generic has to come to market at
23 risk, all it has to do is not file a lawsuit within 45 days.
24 It knows that. It's getting the benefit of the 30-month stay
25 if it has a legitimate basis in exchange for what Congress had

1 specifically provided for was the statutory scheme. But nobody
2 has ever suggested that you could just unilaterally then extend
3 the time beyond it.

4 The rebates set out clear allegations on the sham,
5 but in this case that's the one thing I want to go back to is
6 you have to look at it in the context. None of the other cases
7 that you are going to see, not Schering-Plough, not Valley
8 Drug, not any of the other cases has specifically dealt with
9 the allegation that the Orange Book listing was improper
10 because that in itself is an independent ground. If the Orange
11 Book listing is improper, there's no Noerr-Pennington
12 protection.

13 It's not petitioning, and that's because the FDA does
14 not have discretion. It must accept the branded's word that
15 the patent claims the drug. It has -- it can't do anything.
16 It's been ruled on numerous cases, recently in ADT in the 2nd
17 Circuit that there is no immunity. So PRE doesn't apply to
18 that at all. The only reason it implicates, you know, the
19 patent litigation is because there are two requirements, the
20 proper Orange Book listing and litigation within 45 days. You
21 can have litigation of 45 days and no Orange Book listing.
22 Nobody says that the Orange Book listing that the litigation
23 must be a sham or not a sham. All it says is you have to file
24 a litigation in 45 days, if you file.

25 If you look back at the Hytrin case, In Re Terazosin

1 case that Mr. Meier referred to, one of the interesting points
2 is as to one of these companies they made a mistake. They had
3 an Orange Book listing, but they filed their litigation beyond
4 the 45 days. I think they went to 46 or 47 days. I don't
5 specifically remember. But they missed the date. Just like
6 here they had a problem on the Orange Book listing. They
7 couldn't get the 30-month stay on that, and that was a serious
8 problem. I mean, that is the law. You just can't fudge it or
9 relax it or do anything else.

10 So it's very important to look at from our
11 perspective one has that this is an overall scheme but in
12 context of what was going on. Here they had already kept the
13 generics off the market for the period of time under the
14 30-month stay, and it's only at that point where the generics
15 have come on the market and extended they said -- they went
16 back to them and said, Hey, we can share in the non-profits.
17 You can all do better.

18 And the other point that's there is if, in fact,
19 there's no Orange Book listing, there's no paragraph for
20 certifications, there's no 180 days' exclusivity, the generics
21 would be free to come to market. We have alleged in the
22 complaint which is FDA regulations if there's no paragraph --
23 if there's no Orange Book listing and there is different
24 certifications, the FDA under its regulations typically
25 approves those applications much quicker. They say within six

1 months that's their obligation unless the parties agree to
2 extend it. So all these factors were put on hold because our
3 view is without what they did in the larger overall scheme the
4 product would have been on the market much earlier.

5 That's not to take away, Your Honor, from both
6 together and separate reverse payment cases because if you look
7 at them that's a wrong but if you combine the wrong in context
8 -- and my point is that under Schering-Plough they said look to
9 everything. The administrative law judge did. He made these
10 holdings after, one, considering the validity, the evidence on
11 both sides --

12 THE COURT: Now, didn't the commission reverse him on
13 that --

14 MR. GERSTEIN: The commission reversed him, but the
15 administrative law judge said that they didn't have the right.
16 They didn't sit there, the 11th Circuit, they didn't hear the
17 credibility of the witnesses. They didn't have a basis to
18 basically overturn the administrative law judge which was the
19 fact-finder, but that's exactly what happened. And they
20 specifically go through that line and verse to say why it was
21 improper for the FTC to do that, to actually put in their own
22 version of the facts because he was the finder and they found
23 his evidence more compelling.

24 Now, as a Plaintiff's lawyer who's arguing in other
25 courts in this situation, do I agree with the administrative

1 law judge's conclusions?

2 No. But that's not the point. That was the factual
3 predicate for the 11th Circuit's ruling. So I think it's very,
4 very important to read these cases, you know, in context.

5 The other point is which I just want to address very
6 quickly under Valley Drug and I know -- if I could just hand up
7 a copy of this very quickly. If you look at page 9 in the
8 Valley Drug decision and the quoted language I have from there
9 which is this is the seminal decision in this circuit,
10 Schering-Plough acknowledges specifically -- and I quoted that
11 -- that Valley Drug controls. It's telling you considerations
12 that the Court should deal with in formulating this. And they
13 tell you that, that specifically that these are among the
14 considerations we should consider.

15 There's no hard or fast rule because what they're
16 really asking this Court to do is say what is really going on
17 here, and you'll only know that when you look at the evidence.
18 Was this really payments to keep the generics off the market --

19 THE COURT: Excuse me, Mr. Gerstein. Plaintiffs have
20 five minutes.

21 MR. GERSTEIN: Okay. I'll be very quick, Your Honor.

22 -- or is this specifically something more? Is this a
23 legitimate settlement, or is it something in between?

24 And I highlighted that. But I'd also like to just
25 refer you very quickly to page 12 of the decision where it

1 says, and I quote, "It may be the size of the payment to
2 refrain from repeating sometimes causing reverse payment or
3 exit payment raising suspicion the parties have faith in the
4 validity of the patent, particularly when those payments are
5 non-refundable in the event the patent prevails on the
6 infringement claim as a bond posted as part of the preliminary
7 injunction would be. However, in the instant case, and given
8 the state of the record, it is difficult to infer from the size
9 of the payment alone that the infringement suits lack merit."

10 They are telling you something that's not merely a
11 sham. They are looking and saying look at all the facts that
12 are going on here to basically determine whether or not what
13 these agreements were were really violations of antitrust law
14 or were they really settlements of patent litigation.

15 I just want to just briefly comment on two other
16 points. One is, Your Honor, we have alleged in our complaint,
17 we briefed it, that there is an intergeneric conspiracy under
18 Section 1. Defendants said it's not in our complaint. If you
19 look at paragraph 176 of the complaint, we put in the facts and
20 we have also alleged conspiracy. It's under the standard of
21 Masonite where a patentee basically brokers a settlement among
22 its rivals who was suing under the patent litigation, and we
23 feel that is clearly a basis for the suit.

24 And also they raise on the Orange Book listing that's
25 a throwaway argument that since the Orange Book listings were

1 more than four years ago they're beyond the Statute of
2 Limitations. We are a direct purchaser case who is suing for
3 overcharge. The case law is that each purchase starts the
4 Statute of Limitations. So the fact that conduct that
5 contributed to the harm occurred earlier does not affect when
6 the statute starts. A monopolist is not allowed to get the
7 fruits of its monopoly, and their cause of action occurs at the
8 time of purchase.

9 Thank you, Your Honor.

10 THE COURT: All right, Mr. Gerstein.

11 Plaintiffs have three minutes.

12 MR. HOLZER: Your Honor, Corey Holzer on behalf of
13 the end payer or indirect Plaintiffs. We are going to rest on
14 our briefs with respect for the Court's time and believe the
15 briefs are clear. So that's it for us.

16 THE COURT: All right, Mr. Holzer.

17 MR. RYAN: Thank you, Your Honor.

18 Your Honor, I'm afraid I might be guilty of being
19 unduly polite to the Federal Trade Commission because we
20 weren't going to bring up California. They went to California
21 for the sole purpose of avoiding 11th Circuit law in this case.
22 And the suggestion that we set in California or that we set in
23 front of the Multidistrict Panel that a trial on the patent
24 merits was necessary in this case is -- how should I say it --
25 not quite right, Your Honor.

1 We moved to dismiss in California for the same
2 reasons that we're moving to dismiss here. Now, we didn't have
3 the Schering-Plough as binding precedent in California. At the
4 same time we told Judge Pfaelzer if they're right and there has
5 to be a trial in this case, well, then it's going to be a
6 patent trial. And if there's going to be a patent trial, then
7 it ought to be in front of the Court that had the patent
8 litigation in front of it for three years. That's also what we
9 told the Multidistrict Panel.

10 We have always taken the first position that this
11 case is going to be dismissed no matter where it is. But if
12 there's going to be a trial on the merits, if we are wrong on
13 that and there's going to be a patent trial on the merits which
14 is what the FTC is seeking here -- make no mistake about it.
15 They can say it'd only take a few months, not much discovery.
16 I don't see how you can do the patent trial in this case as
17 easily as the FTC suggests. But if there's going to be a
18 trial, it ought to be in this court.

19 Now, Your Honor, counsel for the FTC does not take
20 issue with our position that the complaint fails to allege that
21 the agreements go beyond the scope of the patent. They don't
22 take issue with that at all. And I think -- I think that ends
23 the case.

24 Now, with respect to our interpretation of
25 Schering-Plough, let me direct the Court to some language that

1 was used by the Federal Circuit in the Cipro case at 544 F.3d
2 1335. Here's what the Federal Circuit said, "We agree with the
3 2nd and 11th Circuits and with the District Court that in the
4 absence of evidence of fraud before the PTO or sham litigation
5 the Court need not consider the validity of the patent in the
6 antitrust analysis of a settlement agreement involving a
7 reverse payment."

8 So that's the Federal Circuit commenting on
9 Schering-Plough, Your Honor, not us. The Court goes on to say,
10 "The 11th Circuit did not consider or rely on evidence of
11 patent invalidity in either Valley Drug or Schering-Plough."

12 So, Your Honor, we return to where we were in our
13 opening remarks which is every court that has considered the
14 issue, every court agrees with us on how to read
15 Schering-Plough and agrees with how the FTC read
16 Schering-Plough until Judge Pfaelzer transferred the case here
17 and until the Multidistrict Panel decided that the cases would
18 be heard here. And the FTC is yet to offer an explanation of
19 how if they believe they were wrong -- they were wrong before
20 -- how they got it so wrong when, in fact, they got it right
21 before and it's today in this court where they are getting it
22 wrong.

23 Now, Your Honor, with respect to Schering-Plough
24 itself, let me just read. We heard some comments about the
25 size and the fact of the payment and the suggestion that if

1 there's no payment then there's no problem. This is from
2 Schering-Plough: "We have said before and we say it again that
3 the size of the payment or the mere presence of a payment
4 should not dictate the availability of a settlement remedy.
5 What we must focus on is the extent to which the exclusionary
6 effects of the agreement fall within the scope of the patent's
7 protection."

8 That's the issue. It's not whether there was a
9 payment. It's not how big the payment was. The issue
10 identified by Schering-Plough is do the agreements extend the
11 scope of that patent, the potential exclusionary effects of the
12 patent. Schering-Plough cannot be read any other way than to
13 say unless there's fraud or unless there's sham litigation you
14 can't come back and attack a settlement and get a full trial on
15 the merits because otherwise these patent cases would never
16 settle.

17 Again, reading from the decision of the 11th Circuit:
18 Finally, the caustic environment of patent litigation may
19 actually decrease product innovation by amplifying the period
20 of uncertainty around the drug manufacturer's ability to
21 research, develop and market the patented product or allegedly
22 infringing product. The intensified guesswork involved with
23 lengthy litigation cuts against the benefits proposed by a rule
24 that forecloses a patentee's ability to settle its infringement
25 claims.

1 Your Honor, the Court is quite clear there is a
2 tremendous social cost that would be realized if these kinds of
3 claims cannot be settled. And, again, we'll say it again. We
4 don't think there's any other way to read Schering-Plough.

5 Now, with respect to the references to the Supreme
6 Court case law, and we do address this in the brief, all of
7 those Supreme Court cases predated Schering-Plough. The FTC
8 argued those very Supreme Court cases to the 11th Circuit.
9 They lost. They shouldn't be in here suggesting that the 11th
10 Circuit misapplied or misunderstood or didn't get Supreme Court
11 precedent right. The 11th Circuit didn't agree with the FTC.
12 They had the arguments in front of them, and they didn't agree
13 with the FTC.

14 Finally, Your Honor, I think that I would cite the
15 Court to one case which was a motion to dismiss on Schering
16 grounds that was granted. Now, it was granted in the Eastern
17 District of New York. But that case can be found at
18 277 F.Supp. 2nd 121. In other words, yes, there was an
19 administrative trial in the Schering-Plough case itself. But
20 from that administrative trial and from the decision in
21 Schering-Plough we now have a rule of law.

22 There's absolutely no reason that that rule of law
23 can't be applied on a motion to dismiss, and we're not aware of
24 any court that has held that it cannot be. It simply hasn't
25 come up as far as we can tell except in this particular

1 decision, Eastern District of New York. It's perfectly
2 appropriate. It's no different an exercise than this Court
3 engages in all the time. What are the required elements of
4 pleading the Plaintiffs' cause of action?

5 If something's missing, if a required element is
6 missing, then the complaint is subject to dismissal. And the
7 required element that's missing here is any allegation that the
8 settlement agreements go outside the exclusionary potential or
9 the scope of the patent.

10 Thank you very much, Your Honor. I appreciate your
11 time.

12 THE COURT: Thank you, Mr. Ryan.

13 Mr. Sunshine, you've got five minutes.

14 MR. SUNSHINE: Thank you, Your Honor. I promise not
15 to use all of that entire length of time in making just a few
16 points. I want to focus on three quick points. None of them
17 will take very long.

18 First, the direct purchaser Plaintiffs have said that
19 they have alleged in paragraph 176 there's allegations of a
20 conspiracy between Watson and Par Paddock. I have read 176
21 more times than I can count. I find that nowhere in paragraph
22 176. It's a rather long paragraph. I won't read it to it,
23 Your Honor.

24 But the sentence that I think that comes closest to
25 arguably supporting that point would be the first sentence of

1 paragraph 176 which says on information and belief Solvay would
2 not have settled with one but not both the generic Defendants.
3 And, of course, Your Honor can go on and read the rest of that
4 paragraph. I don't see anything else in there that covers it.

5 That paragraph speaks just to Solvay's state of mind.
6 It has nothing to do with an agreement between Watson and Par
7 and Paddock. And, of course, even if there were to be some
8 germ of argument in here about parallel conduct and the two
9 generics consciously being aware of these agreements going
10 simultaneously, that's precisely the type of lack of direct
11 interaction between the two supposed co-conspirators that
12 Twombly and the cases before say, you know, it doesn't cross
13 that threshold. So I think you can dispose of the intergeneric
14 conspiracy argument pretty quickly.

15 Secondly, direct purchasers also made a big point
16 about the Orange Book listing. Direct purchasers said that the
17 Orange Book listing is not covered by Noerr-Pennington
18 protection. We agree with that. Everything else after that,
19 of course, we do not agree with.

20 I think that one thing that is important to
21 understand with respect to the Orange Book is that the FDA
22 regulations require that if the branded company believes that
23 the patent covers a listed product or an approved use of the
24 listed product they must put that patent in the Orange Book so,
25 in other words, if the generic company -- the branded company

1 at its peril doesn't list a product that they think is covered.

2 And, in fact, in looking at this we have cited a case
3 in our papers, Your Honor. It is -- pardon me for one second.
4 It's the Twin City Bakery Workers versus Astra where basically
5 the Court had said no Orange Book listing in essence unless the
6 patent was not listed in good faith, it was a sham listing the
7 patent. So it's sort of the same standard coming back all over
8 again.

9 I would also add that with respect to the Orange Book
10 listing there was one mistake in it, one mistake in the patent
11 according to the direct purchaser allegation. The patent had
12 many, many claims. Those other claims were still valid claims
13 and need to be listed. For the Plaintiffs' argument to be
14 ripe, every one of the claims of the patent would have had to
15 have satisfied this Twin City Bakery sham as in effect sham
16 standard. Of course, they clearly cannot do that.

17 And, lastly, on the overall scheme argument, you
18 know, it seems to me that Your Honor hit it right on the head
19 when you said AndroGel and the generics are bioequivalent.
20 This isn't a case about whether there's some real difference
21 between the generics and between the AndroGel product. This is
22 really a case -- and crediting the complaint for at least what
23 it's trying to say, this really is a question of did Solvay
24 botch its prosecution of the patent. It thought it was trying
25 to get a patent on the product AndroGel. It named AndroGel in

1 the patent 227 times.

2 There was a dispute about whether that patent covered
3 or whether it didn't cover. We argue that's the underlying
4 dispute. But now you can't turn an overall scheme argument
5 into really what's one act. It's almost like saying, well,
6 Your Honor, we recognize that it's a baseless litigation claim
7 with respect to the filing of patent prosecution, but don't
8 worry about that piece because it's no overarching scheme.
9 It's almost like saying, well, this is Solvay's scheme. They
10 thought about getting a patent. They researched getting a
11 patent. They put a team together. They filed. They
12 prosecuted the patent. They got the patent. They filed it in
13 the Orange Book, and then they bought a listing.

14 Well, it's really all one single act. It's really
15 all covered by whether the patent is a legitimate and valid
16 patent or not which clearly there was a dispute over. And
17 there is case law that we cite in our papers, Abbott Labs
18 versus Teva, where the Court had said if an element of a
19 Plaintiff's overall scheme is entitled to Noerr-Pennington
20 protection then it cannot be considered as part of an overall
21 scheme. You can't take something that's immune and say, well,
22 okay, we recognize on its own it doesn't violate the antitrust
23 laws. But somehow if I throw it into a broth, it then takes on
24 some other significance.

25 With that, Your Honor, unless you have more

1 questions, I'm done in hopefully less than five minutes.

2 THE COURT: Four minutes, Mr. Sunshine. So,
3 Mr. Gidley, you've got one minute.

4 MR. GIDLEY: Thank you, Your Honor. Very briefly.

5 On the Orange Book, obviously there's no liability.
6 We didn't do anything on the Orange Book listing, so there's no
7 liability for Par or Paddock. As to the argument that the side
8 agreements were not submitted to Your Honor, Valley Drug
9 answers that at 1309: The failure to produce the competing
10 generic drug rather than the payment of money is the
11 exclusionary effect.

12 That's Valley Drug at 1309.

13 The second point, Your Honor, is once valid
14 governmental action has occurred there's no peeking behind the
15 curtain. Just as we don't look at whether Congress was meeting
16 at 1:00 a.m. or whether they had five years of hearings,
17 MedImmune stands for the proposition that we do not put any
18 kind of piercing of what the decisionmaker did.

19 Third, Your Honor, unlike the Cipro consent judgment
20 which is sort of a blank check for a side agreement, our
21 consent judgment lists the various conditions for entry. And
22 that was done publicly; and anyone that was disgruntled, \$60
23 billion, \$80 billion companies in this courtroom suing us today
24 for treble damages, they could have come before Your Honor in
25 September or October of 2006 and moved Your Honor to modify

1 that judgment. They never have.

2 Your Honor, with that I suggest that it's Par
3 Paddock -- and, again, we also didn't hear anything about
4 second filer --

5 THE COURT: Time's up, Mr. Gidley.

6 MR. GIDLEY: Thank you, Your Honor.

7 THE COURT: Well, thank you very much. We will take
8 a very careful look obviously at the issues and get out a
9 written order as soon as we can. I hope all of you get back to
10 wherever you are going safely.

11 Court's in recess until further order.

12 (Proceedings adjourned at 4:16 p.m.)
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C E R T I F I C A T E

UNITED STATES DISTRICT COURT:

NORTHERN DISTRICT OF GEORGIA:

I hereby certify that the foregoing pages, 1 through 85, are a true and correct copy of the proceedings in the case aforesaid.

This the 13th day of January, 2010.

Susan C. Baker, RMR, CRR
Official Court Reporter
United States District Court